DOCKET NO: 285333US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :

MICHEL STREBELLE : EXAMINER: MICALI, JOSEPH

SERIAL NO: 10/567,263 :

FILED: FEBRUARY 6, 2006 : GROUP ART UNIT: 1793

FOR: PROCESS FOR :

REGENERATING A

HYDROGENATION CATALYST

APPEAL BRIEF

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

SIR:

The following is an appeal of the Final Rejection of Claims 10-23 in the above identified application set forth in the Official Action mailed October 29, 2009. A Notice of Appeal was filed on January 28, 2010.

I. REAL PARTY IN INTEREST

The real party of interest is SOLVAY (SOCIETE ANONYME), having an address of RUE DU PRINCE ALBERT, 33, BRUSSELS, BELGIUM B-1050, by virtue of the assignment recorded in the U.S. Patent and Trademark Office on September 6, 2006, reel/frame 018271/0577.

II. RELATED APPEALS AND INTERFERENCES

Appellant/Applicant, Appellant/Applicant's legal representative, and assignee, are aware of no appeals, interferences, judicial proceedings, or cases that are related to, directly affect or would be directly affected by, or have a bearing on the decision of the Board of Patent Appeals and Interferences in this appeal.

III. STATUS OF CLAIMS

Claims 10-23 are the only claims pending in the above-identified application.

Claims 10-23 are rejected and appealed.

Claims 1-9 are cancelled.

IV. STATUS OF AMENDMENTS FILED UNDER 37 C.F.R. § 1.116

An Amendment under 37 C.F.R. § 1.116 has not been filed. A copy of the appealed claims is attached as an Appendix (X).

V. <u>STATEMENT OF JURISDICTION</u>

The Board of Patent Appeals and Interferences (Board) has jurisdiction under 35 U.S.C. § 134.

VI. SUMMARY OF THE CLAIMED SUBJECT MATTER

The invention of claim 10, the only independent claim which is appealed, is directed to a process for regenerating a spent hydrogenation catalyst (specification page 1, lines 1-3) comprising at least one catalytic metal selected from the group consisting of Ru, Rh, Pd, Os, Ir and Pt on an inert support (specification page 1, lines 5-7 and 30-31), wherein the spent catalyst has been used in a hydrogenation reaction of acetylene present in a gas mixture consisting essentially of HCl obtained from the pyrolysis of 1,2-dichloroethane (specification page 4, lines 22-34), wherein the process consists essentially of a thermal treatment of said spent hydrogenation catalyst in the presence of oxygen at a temperature of between 300 and 700 °C (specification page 2, lines 1-2).

No means plus function or step plus function as permitted by 35 U.S.C. 112, six paragraph, are used and therefore none are identified. (37 C.F.R. 41.37 c(1)(v))

VII. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 10-23 stand rejected under 35 U.S.C. 103(a) over Volheim et al., DE 24 38 153 (Volheim or DE '153) in view of Welty, Jr., U.S. 2,368,507 (Welty).

VIII. <u>ARGUMENTS</u>

All arguments and evidence relating to the merits of the rejection under 35 U.S.C. §103(a) on appeal to the Board were presented in Applicant's responses dated March 9, 2009 and September 17, 2009.

The Background and the Invention

In the course of the pyrolysis of 1,2-dichloroethane (DCEa) to form both vinyl chloride monomer (VCM) and HCl a small amount of acetylene is produced which cannot easily be separated from the HCl, owing to their very similar volatilities. When this acetylene-contaminated pyrolysis-generated HCl is then recycled to an oxychlorination reaction to produce more DCEa, the acetylene present therein also reacts and yields various worthless by-products, which are detrimental to the profitability of the overall process. See specification page 1, lines 8-17.

One known method for removing acetylene from pyrolysis-generated HCl is to convert it into ethylene by hydrogenation using a Pd/non-porous silica catalyst described in DE 24 38 153 (i.e., Volheim, cited against the pending

claims). In service, however, this catalyst undergoes gradual deactivation and, although Volheim states, without more, that the catalyst can be regenerated, in practice attempts at such regeneration have proved to be fruitless, owing in particular to the contamination of this catalyst with heavy metals. See specification page 1, lines 17-25 and the article cited there from Chem.-Ing.-Tech. 59 (1987) No. 8, pp. 645-7, filed with its English Abstract in Appellant's IDS on June 5, 2007 and appended herein in Appellant's Evidence Appendix (XI).

In the face of this background, and as explained at specification page 1, lines 26-29, Appellant has *surprisingly* found that if such a contaminated catalyst is treated in the presence of oxygen at a temperature sufficient to remove the contaminations but not too high, so as not to impair the catalyst, the catalyst can nevertheless be regenerated satisfactorily.

Summary of the Argument

The evidence herein will show that in spite of the unsupported general statements in Volheim that the catalyst described therein can be regenerated, those of ordinary skill in the art, including the authors of Volheim, knew otherwise. Accordingly, Appellant's subsequent discovery that when this contaminated catalyst is treated in the presence of oxygen at a temperature of between 300 and 700 °C the catalyst <u>is</u> in fact regenerated satisfactorily is deserving of patent protection.

Detailed Comments

For the limited purpose of this Appeal, and this Appeal alone, all claims stand or fall with Claim 10.

The rejection of Claims 10-23 under 35 U.S.C. 103(a) over Volheim in view of Welty is in error, is unsustainable, and should be REVERSED.

The patent by Volheim (i.e., DE '153) is described in detail in Appellant's specification at page 1, lines 20 ff. Also cited there is an article authored by, among others, Volheim, this article and its English Abstract being appended hereto in Evidence Appendix (XI). Volheim worked for Degussa in Hanau, Germany.¹

The translation of Volheim's patent broadly states that regeneration of the spent catalyst described therein is "economically worthwhile," "technically light" and "possible" (it is this disclosure that the Examiner relies on in rejecting the pending claims). However, no details or suggestions are given in the patent regarding *how* to regenerate the spent catalyst. There is no dispute about this.

The *article* by Volheim paints a very different story regarding Volheim's catalyst's regenerability as compared to the Volheim patent, and supports the statement in Appellant's specification at page 1, lines 22-25 thereof, that

¹ See footnote "**" at the bottom left of page 645 of the Chem.-Ing.-Tech. article appended herein in Appellant's Evidence Appendix (XI) and Volheim's address on the cover sheet of DE '153.

"although the [Volheim patent] records the possibility in theory of regenerating [the spent catalyst], in practice such regeneration has proved to be fruitless, owing in particular to the contamination of this catalyst with heavy metals."

Appellant, in attempting to actually carry out Volheim's supposed "economically worthwhile," "technically light" and "possible" regeneration of his spent hydrogenation catalyst found no useful information in the generalities appearing in the Volheim patent and thus turned to Volheim's employer for direction: Degussa.² In response, Appellant received a letter from Degussa informing them that "no catalyst regeneration [is] possible," recommending instead replacement with fresh catalyst. ³

After receiving this letter, and after much research, Appellant has found, contrary to the indication by the supplier, that the regeneration of the particularly claimed spent hydrogenation catalysts herein <u>can</u> be accomplished relatively easily by thermal treatment in the presence of oxygen at a temperature of between 300 and 700 °C. This finding is completely surprising and unexpected in view of the clear belief to the contrary of those skilled in the art.

For example, in the Declaration of Michel Strebelle, originally filed March 9, 2009, and appended herein in Evidence Appendix (XI), the finding

² Degussa is the supplier of the catalyst Appellant used in the example appearing at specification page 5, lines 10ff.

³ This letter from Degussa, dated 12/7/2000, and its English translation, originally filed March 9, 2009, are appended herein in Appellant's Evidence Appendix (XI).

that the regeneration of the particularly claimed spent hydrogenation catalysts herein can be accomplished by thermal treatment in the presence of oxygen at a temperature of between 300 and 700 °C is described as "completely surprising" (para. 6) in view of the clear belief in the art that it was not possible to regenerate such catalysts. Moreover, this Declaration explains that the fact that thermal treatment has been used to regenerate other types of spent catalysts, such as described in Welty, should not affect the patentability of the present invention, which is directed to the regeneration of catalysts that have become spent by being used in a hydrogenation reaction of acetylene present in a gas mixture consisting essentially of HCl that has been obtained from the pyrolysis of 1,2-dichloroethane (*Id.*).

As recognized in the Strebelle Declaration, Welty does not discuss spent hydrogenation catalysts as claimed herein but, instead, relates to catalysts used in cracking, reforming, dehydrogenation, aromatization, and the like. See column 1, lines 1-7 of Welty and para. 7 of the Strebelle Declaration. The fact that Welty discloses that thermal treatment has been used to regenerate such other types of spent catalysts does not negate patentability herein, or lessen the importance of Appellant's secondary objective evidence of the failure of others. As recently stated by the Federal Circuit in *Bayer Schering Pharma AG v. Barr Laboratories Inc.*, 91 USPQ2d 1569 (Fed. Cir. 2009) "[a]n obviousness analysis is based on several factual inquiries. A court must examine the scope and content of the prior art, the differences between the prior art and the claims at

issue, and the level of ordinary skill in the pertinent art. At that point, a court may consider secondary objective evidence of non-obviousness, such as commercial success, long felt but unsolved need, <u>failure of others</u> and the like."⁴

Moreover, the Strebelle Declaration at paragraph 7 makes it clear that the Examiner commits reversible error in taking the unsupported position that "[w]hat the catalyst was used for matters very little" (page 6, line 7 of the Final rejection) and in concluding that because Welty describes the regeneration of a different catalyst it would have been obvious to try Welty's regeneration conditions to regenerate the catalyst of Volheim.⁵

The Supreme Court has indicated that that an invention *may* be obvious *if*1) it would have been obvious to a person having ordinary skill to try a course of conduct to solve a problem *and* 2) there are a finite number of identified, predictable solutions.⁶ However, the Federal Circuit, post *KSR*, has found two classes where that rule of thumb did not obtain:

⁴ Bayer Schering Pharma AG 91 USPQ2d at 1572 (emphasis added, citations omitted).

⁵ Welty does not discuss spent hydrogenation catalysts used in a <u>hydrogenation</u> reaction of acetylene present in a gas mixture consisting essentially of HCl obtained from the pyrolysis of 1,2-dichloroethane as claimed herein but, instead, relates to catalysts used in cracking, reforming, <u>de</u>hydrogenation, aromatization, and the like. See col. 1, lines 1-6 of the reference and paragraph 7 of the Strebelle Declaration.

⁶ KSR International Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007).

First, an invention would not have been obvious to try when the inventor would have had to try all possibilities in a field unreduced by direction of the prior art. When "what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful" an invention would not have been obvious. *O'Farrell*, 853 F.2d at 903. This is another way to express the *KSR* prong requiring the field of search to be among a "finite number of identified" solutions.

Second, an invention is not obvious to try where vague prior art does not guide an inventor toward a particular solution. A finding of obviousness would not obtain where "what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *O'Farrell*, 853 F.2d at 903. This expresses the same idea as the *KSR* requirement that the identified solutions be "predictable."

Bayer Schering Pharma AG 91 USPQ2d at 1573 (citations omitted).

In the present case, Volheim in no way limits the parameters or the numerous possible choices one of ordinary skill in the art faces in attempting to regenerate a catalyst. In addition, Volheim is unquestionably a reference that constitutes "vague prior art [that] does not guide an inventor toward a particular solution" as the reference provides absolutely <u>no</u> guidance with regard to any conditions for regeneration of spent catalyst. That Welty describes one set of conditions for the regeneration of a *different* catalyst does not change the fact that the disclosure in Volheim, even when taken with Welty, squarely falls within the exceptions noted above given the absolute lack of a finite number of

identified, predictable solutions available to one of ordinary skill interested in regenerating a particular catalyst. The fact that the Examiner, through hindsight, was able to find one example of thermal catalyst regeneration for a different catalyst does not change this analysis, which is forward looking and which must take into account all of the possibilities faced by one attempting to regenerate the catalyst of Volheim which, when all the evidence of record herein is considered, was viewed by those of skill in the art to be nonregenerable.

Thus, the Welty catalysts, when spent, are not those of the present claims or those of Volheim. Because the catalysts of the present invention and Volheim are used in a different reactive environment, and for a completely different reaction (hydrogenation), as compared with the Welty catalysts used for example in dehydrogenation, the materials and conditions responsible for the decrease in catalytic activity in Welty which must be reversed/removed in order to provide regeneration are completely distinct and different from those here and in Volheim. See para. 7 of the Strebelle Declaration.

In addition, and because the art taken as a whole clearly recognized the particular spent hydrogenation catalysts regenerated herein as unregenerable, and provided absolutely no guidance with regard to any possible conditions for such regeneration, the fact that Appellant has succeeded in doing so is deserving of patent protection. As the Federal Circuit observed in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), long felt but unsolved needs and

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the failure of others is an important factor to be weighed in favor of Applicant in the obvious determination:

"Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17–18, set out an objective analysis for applying §103: "[T]he scope and content of the prior art are ... determined; differences between the prior art and the claims at issue are ... ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." (emphasis added)

Accordingly, and in view of the understanding in the art regarding the supposed unregenerability of the particular spent hydrogenation catalysts being regenerated here, and, even absent this knowledge, because there were *not* a finite number of identified predictable solutions to the regeneration problem solved herein, Appellant submits that the rejection under 35 U.S.C. 103(a) over Volheim in view of Welty is in error and should be REVERSED.

IX. CONCLUSION

Appellants submit that in view of the deficiencies noted above, the decision of the Examiner must be reversed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, L.L.P.

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 $\begin{array}{c} \text{Customer Number} \\ 22850 \end{array}$

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CLAIMS APPENDIX X

Claims 1-9 (Canceled).

Claim 10 (Previously Presented): A process for regenerating a spent hydrogenation catalyst comprising at least one catalytic metal selected from the group consisting of Ru, Rh, Pd, Os, Ir and Pt on an inert support, wherein the spent catalyst has been used in a hydrogenation reaction of acetylene present in a gas mixture consisting essentially of HCl obtained from the pyrolysis of 1,2-dichloroethane, wherein the process consists essentially of a thermal treatment of said spent hydrogenation catalyst in the presence of oxygen at a temperature of between 300 and 700 °C.

Claim 11 (Previously Presented): The process according to Claim 10, wherein the catalytic metal is Pd.

Claim 12 (Previously Presented): The process according to Claim 10, wherein the inert support is based primarily on silica.

Claim 13 (Previously Presented): The process according to Claim 10, wherein the inert support has a BET surface area of less than $5 \text{ m}^2/\text{g}$.

Claim 14 (Previously Presented): The process according to Claim 10, wherein the temperature during the thermal treatment is between 400 and 600°C.

Claim 15 (Previously Presented): The process according to Claim 10, wherein the thermal treatment takes place in the presence of air.

Claim 16 (Previously Presented): The process according to Claim 10, wherein the thermal treatment consists in a residence in a stove or a ventilated electric oven.

Claim 17 (Previously Presented): The process according to Claim 10, wherein the catalyst is contaminated with traces of heavy metals.

Claim 18 (Previously Presented): A process for synthesizing vinyl chloride monomer by coupling a direct chlorination and an oxychlorination of ethylene to form 1,2-dichloroethane, which is converted primarily into vinyl chloride monomer and into HCl by pyrolysis, the HCl containing traces of acetylene and being recycled to the oxychlorination following hydrogenation of these traces of acetylene in the presence of a catalyst regenerated by the process according to Claim 10.

Claim 19 (Previously Presented): The process according to Claim 10, wherein the concentration of the catalytic metal in the catalyst is greater than or equal to 0.01% and less than or equal to 10% by weight relative to the total weight of the catalyst.

Claim 20 (Previously Presented): The process according to Claim 10, wherein the support has a specific surface area measured in accordance with the BET method with nitrogen of less than 5 m²/g, an average pore volume of less than 0.01 ml/g, and a particle size between 1 and 20 mm, said catalytic metal being present thereon in a layer of less than or equal to a micron in the form of crystallites having a size of between 0.1 and 0.5 µm.

Claim 21 (Previously Presented): The process according to Claim 20, wherein the support has a specific surface area of less than 1 m²/g and a particle size between 3 and 7 mm.

Claim 22 (Previously Presented): The process according to Claim 10, wherein the catalyst is beads of silica that are 3 to 5 mm in diameter with 0.15% of Pd supported at the surface thereof and having a specific surface area of less than $1 \text{ m}^2/\text{g}$.

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Claim 23 (Previously Presented): A process for synthesizing vinyl chloride monomer by coupling a direct chlorination and an oxychlorination of ethylene to form 1,2-dichloroethane, which is converted primarily into vinyl chloride monomer and into HCl by pyrolysis, the HCl containing traces of acetylene and being recycled to the oxychlorination following hydrogenation of these traces of acetylene in the presence of a catalyst regenerated by the process according to Claim 22.

EVIDENCE APPENDIX XI

- 1. Chem.-Ing.-Tech. 59 (1987) No. 8, pp. 645-7, filed with its English Abstract.
 - 2. Degussa letter, dated 12/7/2000, and its English translation.
 - 3. Declaration of Michel Strebelle, originally filed March 9, 2009.
- 4. Bayer Schering Pharma AG v. Barr Laboratories Inc., 91 USPQ2d 1569 (Fed. Cir. 2009)
 - 5. KSR International Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007).

1. Chem.-Ing.-Tech. 59 (1987) No. 8, pp. 645-7, filed with its English Abstract.

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ANSWER 1 OF 1 HCA COPYRIGHT 2006 ACS on STN
L9
     107:198949 HCA Full-text
AN
     Entered STN: 27 Nov 1987
ED
     Selective hydrogenation of acetylene in the manufacture of vinyl chloride
TΙ
     Mueller, Herbert; Deller, Klaus; Vollheim, Gerhard; Kuehn,
AII
CS
     Geschaeftsbereich Anorg. Chemieprod., Degussa, Hanau, 6450/1, Fed. Rep.
     Ger.
     Chemie Ingenieur Technik (1987), 59(8), 645-7
SO
     CODEN: CITEAH; ISSN: 0009-286X
DT
     Journal
     German
I.A
CC
     35-2 (Chemistry of Synthetic High Polymers)
     CASREACT 107:198949
       In the title hydrogenation (for removal of byproduct C2H2), the initial linear region of C2H2 conversion
AB
       was 0 order and to attain the maximum C2H4 production, the temperature of the throughput had to be
       changed frequently for the reactors. C2H2 residue of <10 ppm could be attained at space velocity >2200/h
       by controlled temperature which should not exceed 180°. Selectivity increased with increasing use time
       for hydrogenation catalyst E 39H with a maximum 76% selectivity attained after 4 yr. Catalyst selection
       and the hydrogenation mechanism were discussed.
     acetylene hydrogenation ethylene selectivity; catalyst acetylene
ST
     hydrogenation ethylene; vinyl chloride acetylene selective hydrogenation
     Hydrogenation catalysts
IT
        (selective, for acetylene to ethylene, vinyl chloride preparation in
        relation to)
     111214-16-5
IT
     RL: CAT (Catalyst use); USES (Uses)
        (catalysts, for hydrogenation of acetylene to ethylene, vinyl chloride
        preparation in relation to)
     74-86-2, Acetylene, reactions
     RL: RCT (Reactant); RACT (Reactant or reagent)
        (hydrogenation of, selective, to ethylene, in vinyl chloride preparation)
     74-85-1P, Ethylene, preparation
тт
     RL: SPN (Synthetic preparation); PREP (Preparation)
        (preparation of, by selective hydrogenation of acetylene, vinyl chloride
        preparation in relation to)
     75-01-4P, Vinyl chloride, preparation
TТ
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RL: SPN (Synthetic preparation); PREP (Preparation)

(preparation of, selective hydrogenation of byproduct acetylene in)

Kurzmitteilungen

Die selektive Hydrierung von Acetylen im Herstellungsverfahren für Vinylchlorid

Herbert Müller, Klaus Deller, Gerhard Vollheim und Wenzel Kühn**

1 Problemstellung

Vinylchlorid (VCM) ist heute eines der wichtigsten Monomere zur Herstellung einer Vielzahl von technisch interessanten Polymerisaten. Seit Beginn der Produktion in den 30er Jahren hat eine sehr schnelle Marktentwicklung zu einer derzeitigen Weltjahresproduktion von ca. 18,5 Mio. t geführt.

Vinylchlorid wird weltweit in modernen Großanlagen überwiegend nach kombinierten Verfahren hergestellt, die den ursprünglichen, auf der Addition von HCl an Acetylen basierenden Prozeß fast vollständig abgelöst haben [1]. In Abb. 1 ist ein heute gängiges VC-Herstellungsverfahren schematisch dargestellt. Die übliche Dichlorethan-(EDC-)Herstellung aus Ethylen und Chlor wird dabei mit der Oxichlorierung des Ethylens kombiniert und das Roh-EDC aus beiden Stufen gemeinsam gereinigt. Die anschließende thermische Dehydrochlorierung des EDC zu Vinylchlorid erfolgt in einem Spaltofen bei ca. 500 bis 600 °C und 30 bis 45 bar. In der VC-Abtrennung wird der über Kopf gewonnene Chlorwasserstoff in die Oxichlorierungsstufe rückgeführt, so daß der gesamte, bei der EDC-Spaltung gebildete Chlorwasserstoff wieder verbraucht wird.

An Verunreinigungen enthält dieser Chlorwasserstoff neben Spuren von VCM und Rest-Ethylen hauptsächlich Acetylen in Mengen bis zu 2000 ppm, das bei der EDC-Pyrolyse durch HCl-Abspaltung aus VCM in einer Folgereaktion entsteht. Abb. 2 zeigt die dem Verfahren zugrundeliegenden Reaktionsgleichungen.

Das Acetylen stört besonders in der Oxichlorierungsstufe, da es dort teilweise zu CO₂ oxidiert wird, aber auch die Bildung höher chlorierter Ethane verursacht. Daraus resultiert vor allem ein Mehrverbrauch an Chlor und Ethylen im gesamten Verfahren.

Als Maßnahme zur Verbesserung der Wirtschaftlichkeit des VC-Herstellprozesses hat sich der Einbau einer zusätzlichen Verfahrensstufe bewährt, in der Acetylen selektiv zu Ethylen hydriert wird. Damit kann nicht nur der bei Anwesenheit von Acetylen zu verzeichnende Chlor-Verlust minimiert, sondern zusätzlich das Einsatzprodukt Ethylen zurückgewonnen werden bei gleichzeitiger Verringerung des Acetylen-Gehaltes auf unter 10 ppm.

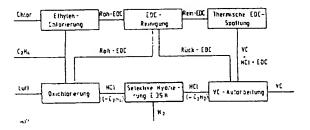
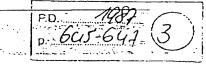


Abb. 1. Schema des VC-Herstellungsverfahrens mit selektiver Hydrierung von Acetylen.



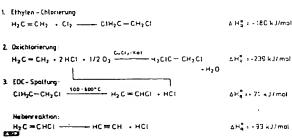


Abb. 2. Reaktionsgleichungen im VC-Herstellungsverfahren.

2 Die selektive Hydrierung von Acetylen

2.1 Reaktionsmechanismus

Die selektive Hydrierung von Acetylen zu Ethylen wurde in der Literatur vielfach beschrieben [2-4]. Sie wird heterogen-katalytisch überwiegend an Edelmetall-Trägerkatalysatoren durch Zudosieren einer bezüglich Acetylen überstöchiometrischen Menge Wasserstoff durchgeführt. Der Mechanismus läßt sich wie in Abb. 3 gezeigt darstellen [5].

Wasserstoff liegt im adsorbierten Zustand als atomar gebundene Oberflächenspezies an Palladium vor. Die H-Atome besitzen eine große Beweglichkeit auf der Katalysatoroberfläche. Acetylen ist über eine Zweizentrenbindung an beiden C-Atomen adsorbiert. Im ersten Schritt der Oberflächenreaktion fin. et H-Addition an adsorbiertes Acetylen statt, wobei eine partiell hydrierte Vinylzwischenstufe entsteht. Diese setzt sich durch Anlagerung eines weiteren H-Atoms zum gewünschten Produkt Ethylen um, welches entweder sofort desorbiert oder auch teilweise noch vor der Desorption zum unerwünschten Ethan durchhydriert wird. Neben der Ethan-Bildung können vor allem störende Polymerisations- und Verkokungsreaktionen auftreten, die zur Desaktivierung des Katalysators führen. Um das Reaktionsgeschehen möglichst selektiv in Richtung Ethylen-Bildung zu lenken, kommt der Wahl eines geeigneten Katalysatorsystems entscheidende Bedeutung zu.

2.2 Katalysatorauswahl

a) Wahl der aktiven Komponente. Aus zahlreichen empirischen Untersuchungen geht hervor, daß Palladium sowohl im Hinblick auf die Aktivität als auch auf die Selektivität für diese Reaktion das geeignete Edelmetall darstellt [6]:
Aktivität:

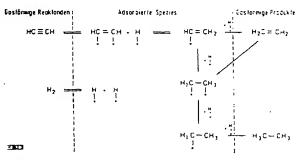


Abb. 3. Mechanismus der Acetylen-Hydrierung an Edelmetall-Katalysatoren.

Vortrag von K. Deller auf der Dechema-Jahrestagung, 5./6. Juni 1986 in Frankfurt/M.

Dr. K. Deller, Dipl.-Ing. H. Müller und Dr. G. Vollheim, Degussa, Geschäftsbereich Anorganische Chemieprodukte. Postfach 13 45. 6450 Hanau I. und Dr. W. Kühn, Hoechst Aktiengesellschaft, Werk Gendorf, 8269 Gendorf.

Fehlmenge immer geringer. Gleichzeitig konnte ein Anstieg der Selektivität beobachtet werden. Es findet demnach eine Formierphase des Katalysators statt, in der sich eine gewisse Coke-Beladung auf der Katalysatoroberfläche einstellt. Dabei werden vermutlich stärker aktive Zentren blockiert, welche die unselektive Durchhydrierung zum Ethan katalysieren.

Der Katalysator erreichte nach annähernd vier Betriebsjahren ein Maximum von ca. 76 % Selektivität, die gegen Ende der Standzeit wieder etwas abfiel. Trotz der stark schwankenden und teilweise sehr hohen Belastung hat der Katalysator schließlich eine Standzeit von neun Jahren erreicht. Der Umsatz lag dabei stets deutlich über 99 %. Die Analyse des gebrauchten Katalysators zeigte, daß neben ca. 3 % Kohlenstoff-Ablagerungen auf der Katalysatoroberfläche auch die Anreicherung von Schwermetallen (Eisen, Titan etc. aus Reaktormaterial, Hg aus H₂-Strom) wohl zum endgültigen Aktivitätsverlust geführt haben.

Die Wiederaufarbeitung des gebrauchten Katalysators gelang mit hoher Edelmetall-Rückgewinnungsquote. Bei Katalysatoren, deren Desaktivierung allein auf Kohlenstoff-Ablagerungen zurückzuführen ist, kann auch eine Regenerierung erfolgen.

Die Autoren möchten sich für die tatkräftige Unterstützung und die wertvolle Mitarbeit an diesem Projekt bei den Herren Brandstetter, Dr. Oberrauch, Dr. Riedl, Schwarzmaier und Trost (Hoechst AG, Werk

Gendorf) sowie den Herren Dr. Kastenhuber, Dipl.-Ing. Mösinger und Dr. Strätz (Degussa AG) ganz herzlich bedanken.

Eingegangen am 15. Oktober 1986 [K 862]

Literatur

- [1] Ullmanns Encyklopädie der Technischen Chemie, Bd. 9, Butadien bis Cytostatica, VCH-Verlag, Weinheim/Bergstr. 1975.
- [2] Bond, G. C.: Catalysis by Metals, Academic Press, London-New York 1962.
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Die Bildung von Oligomeren des Propylens in Mischungen von Propylen und Wasser bei hohen Drücken und Temperaturen

Harro Lentz und Miguel Sanchez*

Die Oligomeren-Bildung (hier oft einfach Polymerisation genannt) des Ethylens in Gegenwart saurer Katalysatoren (AlCl₃, BF₃) ist zur Erzeugung von Schmierölen ("Buna-Öl") ausgenutzt worden. Von Propylen ist die Polymerisation zu öhrtigen Substanzen bekannt und wurde im besonderen zur Herstellung des Tetrameren Isododecylen (190 °C, 50 bar, Phosphorsäure-Kontakt) ausgenutzt.

Auch in Mischungen aus Wasser und Propylen setzt bei hohen Drükken und Temperaturen Polymerisation ein und stört Versuche zur Bestimmung des Phasengleichgewichtes [1]. Der Versuch, das Löslichkeitsverhalten eines C₆-Olefins in Wasser in der Umgebung der kritischen Lösungstemperatur zu untersuchen, führte ebenfalls zu Störungen durch Dimerisation [2].

Die Polymerisation von Olefinen in Mischungen mit Wasser erscheint unter einigen Aspekten interessant zu sein: Wasser könnte die Reaktion direkt beeinflussen, oder es könnte als Lösungsmittel für dritte Stoffe dienen, die sich in dem reinen Gas nicht lösen würden. Hydrothermale Lösungen werden für die Geochemie des Erdöls Bedeutung haben. Andererseits kann komprimierter Wasserdampf von hoher Temperatur zur besseren Ausbeutung von Erdöllagerstätten eingesetzt werden, wöbei die Frage möglicher Reaktionen mit dem Öl oder zugehöriger Gase geklärt sein müßte. Für die Polymerisation des Ethylens bei hohen Drücken ist vorgeschlagen worden, die problematische Wärmeführung der Reaktion durch Zusatz von Wasser zu verbessern (Übersicht über die Patentliteratur s. [3]).

Diese Arbeit hat das Ziel, erste Versuche über das Auftreten und den Ablauf der Polymerisationsreaktion bei Wasserzusatz zu machen und Informationen über die Eigenschaften der so gebildeten Produkte zu gewinnen.

1 Experimentelles

Einige Experimente sind nach einem Verfahren [4] gemacht worden, bei dem der Druck in Abhängigkeit von der Temperatur bei fest eingefüllten Mengen und konstanten Volumina direkt registriert wurde. Die Meßsubstanz konnte außerdem durch ein Fenster aus synthetischem Saphir beobachtet werden.

Einfacher lassen sich Versuche bei konstantem Volumen ohne dauernde Druckmessungen ausführen. Als Reaktionsgefäß diente ein Autoklav, der aus einem zylindrischen Stahlrohr (AISI Typ 316) von 304 mm Länge, 14,3 mm Außen- und 4,7 mm Innendurchmesser gebildet wurde. Das eine Ende war durch einen Blindverschluß geschlossen, und das andere führte über eine kurze Kapillare zu einem Hockdruckventil. In dem Blindverschluß war ein Miniatur-Mantelthermoelement aus Chromel-Alumel mit einem äußeren Durchmesser von 0,5 mm hart eingelötet. Mit diesem Thermoelement konnte die genaue Temperatur im Inneren der Zelle gemessen werden. Der Autoklav wird durch eine elektrische Widerstandsheizung außen beheizt und die entsprechende Temperatur über Thermoelemente auf der Wand der Meßzelle geregelt. Die Packung des Ventils wird durch eine Kühlung vor zu großer Hitze geschützt.

Der Autoklav wurde über das Ventil mit Propylen gefüllt, das aus einem Vorratsbehälter entnommen wurde, der vor und nach der Entnahme genau gewogen werden konnte. Dann wurde aus einer Spindelpresse Wasser hinzugepreßt, dessen Menge aus den Umdrehungen der Spindel bestimmt wurde. Der Druck konnte auf Bourdon-Manometern abgelesen werden. Die Versuche wurden bei konstantem Volumen ausgeführt. Der sich für die jeweiligen Temperaturen einstellende Druck läßt sich abschätzen und kann durch Testmessungen kontrolliert werden, indem die Manometer auf den geschätzten Druck eingestellt werden und dann das Ventil zum Autoklaven kurz

Prof. Dr. H. Lentz, Universität-GH Siegen, Fachbereich 8, Postfach 1012 40, 5900 Siegen, und M. Sanchez, Departamento de Fisico-Quimica Aplicada, Facultad de Farmacia, Universidad de Sevilla, E-41012 Sevilla.

Degussa letter, dated 12/7/2000, and its English translation.

2.



Degussa-Hüls AG

Sivento Claus Bauer

Дπ

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(059)218-2053 (069)218-3392

An Fax

00492843-73-3744

Datum

12.07.2000

Kd-Betroff E39H / Beurteilung von gebrauchtem Katalysator

Seiten

Sehr geehrter Herr Temath,

bezugnehmend auf die Bemusterung Ihres gebrauchten Katalysators E39H haben wir eine Bewertung dieses Katalysators vorgenommen. Dieser Katalysator entstammt unserer letzten Lieferung von 1992.

Folgende Beurteilungen wurden durchgeführt:

- 1) Visuelle Beurteilung
- 2) Kohlenstoff-Ablagerungen (Quantitative C-Bestimmung)
- 3) Semiquantitative Röntgenfluoreszenzanalytik (RFA)
- 4) Labor-Performancatest

1) Visuelle Beurteilung :

Der Katalysator weist beträchtliche Ablagerungen an der Oberfläche auf (Kohlenstoff-Ablagerungen). Diese Ablagerungen sind durch einfache Siebungprozeduren oder Waschvorgänge nicht zu entfernen.

2) Quantitative C-Bestimmung

Fischer Katalysator:

0 Gew% C

E 39 H Solvin:

0,7% (+/- 0,05) Gaw% C

Hoher Anteil an Kohlenstoffablagerungen !

3) Semiquantitative RFA

Die Werte spjegeln Größenordnungen der Elementgehalte wieder. Je nach Matrixeinfluß können beträchtliche Abweichungen auftreten.

Elemente:	Frischer E 39 H Katalyeator	Solvin Katalysator gebraucht
Pd [Gew%]	0,15	0.14
CI-Abiagerung (anorg) [Gew%]	0,015	1,09
Fe (ppm)	< 50	84
Spuren	-	Co/Zn/Cu/Ti/Pb/Zr

Mäßige Erhöhung an Fe-Beladung (Fe= Katalysatorgift) Cl-Ablagerungen weisen zuf einen hohen Oberflächenablagerungsanteil hin.

4) Labor Performancetest:

GHSV:

20.000/h

Testgas:

99,3% Stickstoff / 0,5% Wasserstoff / 0,2% Acetylen

Temp.:

100-190°C

Erfassung:

Acetylenumsatz

Temperatur Realstor [°C]	Mindestumsatz friecher Katalysator [%]	Umsatz Solvin Katalysator [%]
130°C	60	6,5
160°C	70	10

Der gebrauchte Kastalysator von Solvin hat eine sehr geringe Kydrieraktivität bezüglich Acetylen (siehe auch Auswertungsgraph im Anhang).

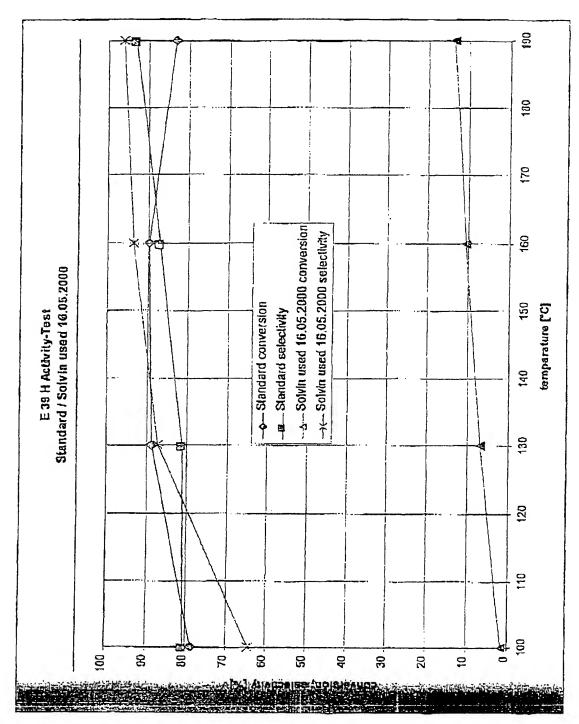
Zusammenfassung (Bewortung)

Der bemusterte Katalysator von Solvin ist ein sehr inaktiver Katalysator mit hohen Kohlenstoff-Ablagerungen an der Oberfläche. Eine außergewöhnliche Vergiftung liegt nicht vor. Somit zeigt der Solvin-Katalysator das Bild eines Katalysatora der aufgrund seiner Einsatzzeit eine für diesen Katalysatortyp typische Deaktivierung infolge Alterung durch Oberflächenablagerungen erfuhr. Diese Oberflächenablagerung ist durch einfache Waschungen oder Siebungsprozeduren nicht zu entfernen (keine Katalysatorregenerierung möglich). Die Empfehlung ist deshalb ein Ersatz der Reaktorcharge durch Frischkatalysator.

Mit freundlichen Graßen Degussa-Hols AG

A Claus Bayer

Anhang



FAX

Degussa-Hüls AG Sivanto Claus Bauer

To

To Solvin Kunststoffe GmbH

Solvay Kunststoffe GmbH

Mr Temath Rheinberg

47493 Rheinberg Germany Department Telephone Fax

 \bowtie

SV-IK-CK (069)218-2053 (069)218-3392

To Fax

00492843-73-3744

Date

12.07.2000

Customer Ref.

E39H / Assessment of used catalyst

Pages

3

Dear Mr Temath,

In reference to the inspection of your used E39H catalyst we have undertaken an assessment of this catalyst. This catalyst comes from our last delivery of 1992.

The following assessments were performed:

- 1) Visual assessment
- 2) Carbon deposits (quantitative C-assessment)
- 3) Semi-quantitative x-ray fluorescence analysis (XFA)
- 4) Laboratory performance test
- 1) Visual assessment:

The catalyst shows considerable deposits on the upper surface (carbon deposits). These deposits cannot be removed through simple sieving procedures or washing measures.

2) Quantitative C-determination

Fresh catalyst:

0 weight% C

E 39 H Solvin:

0.7% (+/- 0.05) weight% C

High proportion of carbon deposits

3) Semi-quantitative XFA

The values reflect orders of magnitude of the element contents. Depending on the matrix influence significant deviations could occur.

Elements	Fresh E 39 H catalyst	Used Solvin catalyst
Pd (weight%)	0.15	0.14
Cl deposit (inorg.) [weight%]	0.015	1.09
Fe [ppm]	< 50	84
Traces	-	Co/Zn/Cu/Ti/Pb/Zr

Moderate increase in Fe load (Fe = catalyst poison) Cl deposits point to a high proportion of surface deposits.

4) Laboratory performance test

GHSV:

20,000/hour

Test gas:

99.3% nitrogen / 0.5% hydrogen / 0.2% acetylene

Temp.:

100-190°C

Detection:

Acetylene conversion

Reaction temperature [°C]	Minimum conversion fresh catalyst [%]	Conversion Solvin catalyst [%]
130° C	60	6.5
160° C	70	10

The used Solvin catalyst has very poor hydrogenating activity with regard to acetylene (see also evaluation graph in appendix).

Summary (assessment)

The Solvin catalyst that was inspected is a very inactive catalyst with a high level of carbon depositing on the surface. There is no unusual poisoning. Consequently the Solvin catalyst shows the signs of a catalyst which on the basis of its time in service has experienced a deactivation through surface deposits typical for this type of catalyst as a consequence of ageing. These surface deposits cannot be removed through simple washing or filtering procedures (no catalyst regeneration possible). The recommendation therefore is to replace the reactor charge with a fresh catalyst.

Yours sincerely, Degussa-Hüls AG

pp Claus Bauer Appendix pp Stefan Bösing

E 39 H Activity Test Standard / Solving used 16.05.2000

Standard conversion Standard selectivity Solving used 16.05.2000 conversion Solving used 16.05.2000 selectivity

temperature [°C]

Degussa-Hüls

3. Declaration of Michel Strebelle, originally filed March 9, 2009.

DOCKET NO: 28533US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF

:

MICHEL STREBELLE

: EXAMINER: MICALI, JOSEPH

SERIAL NO: 10/567,263

.

FILED: FEBRUARY 6, 2006

: GROUP ART UNIT: 4181

FOR: PROCESS FOR REGENERATING A HYDROGENATION CATALYST

DECLARATION OF MICHEL STREBELLE

SIR:

Now comes Michel Strebelle, who declares and states:

- 1. That I am the inventor of the above-identified patent application.
- 2. That the process described in the above-identified U.S. patent application relates to regenerating a spent hydrogenation catalyst containing at least one catalytic metal selected from Ru, Rh, Pd, Os, Ir and Pt on an inert support, where the spent catalyst has been used in a hydrogenation reaction of acetylene present in a gas mixture containing essentially of HCl, the HCl being obtained from the pyrolysis of 1,2-dichloroethane. The regeneration process described is essentially a thermal treatment of this particular spent hydrogenation catalyst in the presence of oxygen at a temperature of between 300 and 700°C.
- 3. As explained at specification page 1, in the production of vinyl chloride monomer, 1,2-dichloroethane is subjected to pyrolysis to form vinyl chloride monomer on the one hand, and HCl on the other. In the course of this pyrolysis a small amount of acetylene is also produced, but this acetylene is not easily separated from the HCl due to their very similar

volatilities. If this HCl is recycled to the oxychlorination, the trace of acetylene present therein is also recycled, and it gives rise to worthless by-products which are detrimental to the overall profitability of the process.

- 4. One known method for removing the acetylene from the HCl referred to in 3. above is by converting it into ethylene by hydrogenation in the presence of a catalyst. Once such catalyst is described in DE 24 38 153 which is described in detail at specification page 1, lines 20 ff, as is the difficulty in regenerating the particular spent catalyst at issue in this patent application. In addition, the specification cites an article by Mueller.
- 5. Both DE '153 and Mueller are publications of Degussa, the supplier of the catalyst E39H used in the example appearing in the specification at page 5, lines 10ff.

 Consistent with both DE '153 and Mueller, Solvay, my employer, received a letter from Degussa concerning this catalyst, its inactivation through use, and its possible regeneration. This letter specifically states "no catalyst regeneration possible", recommending instead replacement with fresh catalyst.
- 6. Contrary to this indication of nonregenerability, and as explained at specification page 1, lines 26ff, I have found, surprisingly, that the regeneration of the particular spent hydrogenation catalysts described in my application can be accomplished by thermal treatment in the presence of oxygen. This finding is completely surprising in view of the clear prior belief by others that it was not possible to regenerate such catalysts. The fact that thermal treatment has been used to regenerate other types of spent catalysts does not in any way predict or suggest that thermal treatment in oxygen would be successful in the regeneration of catalysts that have become spent by being used in a hydrogenation reaction of

acetylene present in a gas mixture consisting essentially of HCl that has been obtained from the pyrolysis of 1,2-dichloroethane.

- 7. It is my understanding that U.S. 2,368,507 to Welty has been cited in rejecting the claims to my invention. However, Welty does not discuss spent hydrogenation catalysts like those of my invention but, instead, relates to catalysts used in cracking, reforming, dehydrogenation, aromatization, and the like. See column 1, lines 1-7 of Welty. Thus, the Welty catalysts, when spent, are not those of my invention or those of DE '153. Because the catalysts of my invention and DE '153 are used in a different reactive environment, and for a completely different reaction (hydrogenation), as compared with the Welty catalysts, the materials and conditions responsible for the decrease in catalytic activity of the Welty catalysts, which must be reversed/removed in order to provide regeneration, are completely different from and unrelated to those of my invention and DE '153. Thus, what Welty describes in no way would suggest what I have done, even in combination with the contents of DE '153, as one would not expect to be able to apply the Welty teachings to the DE '153 catalysts due to the completely different reactions and reaction environments being discussed.
- 8. In my opinion the fact that I have succeeded in regenerating a specific type of spent hydrogenation catalyst that was clearly recognized in this field as being unregenerable is deserving of patent protection.
- 9. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believe to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under

Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

10. Further deponent sayeth not.

March, 9th ofloog

Bayer Schering Pharma AG v. Barr Laboratories Inc., 91 USPQ2d
 1569 (Fed. Cir. 2009)

Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > Bayer Schering Pharma AG v. Barr Laboratories Inc., 91 USPQ2d 1569 (Fed. Cir. 2009)

Bayer Schering Pharma AG v. Barr Laboratories Inc., 91 USPQ2d 1569 (Fed. Cir. 2009)

91 USPQ2d 1569
Bayer Schering Pharma AG v. Barr Laboratories Inc.
U.S. Court of Appeals
Federal Circuit
No. 2008-1282
Decided August 5, 2009
575 F3d 1341

Headnotes

PATENTS

[1] Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (▶115.0903.03)

Patent claiming oral contraceptive containing active ingredient drospirenone, delivered in micronized form in "normal,"uncoated pill, is invalid as obvious to try, since person of ordinary skill in art, viewing relevant prior art references in seeking to solve problem of delivering acid-sensitive but hydrophobic drospirenone, would be required to choose between known options of micronized drospirenone delivered by normal pill, and drospirenone delivered by enteric-coated pill, since this is finite number of options, and formulator of ordinary skill thus would not have been required to try all possibilities in field unreduced by prior art, since prior art was not vague in pointing toward general approach or area of exploration, and instead guided formulator precisely to use of either normal pill or enteric-coated pill, and since selection of micronized drospirenone in normal pill led to result anticipated by prior art in vivo studies.

Particular Patents

Particular patents — Chemical — Oral contraceptives

6,787,531, Hilman, Heil, Lipp, Heithecker, Huempel, and Tack, pharmaceutical composition for use as a contraceptive, judgment of invalidity affirmed.

Case History and Disposition

Appeal from the U.S. District Court for the District of New Jersey, Sheridan, J.

Action by Bayer Schering Pharma AG and Bayer Healthcare Pharmaceuticals Inc. against Barr Laboratories Inc. for patent infringement. Plaintiffs appeal from judgment holding patent invalid for obviousness. Affirmed; Newman, J., dissenting in separate opinion.

Attorneys

Peter B. Bensinger Jr. and Lawrence D. Rosenberg, of Bartlit Beck Herman Palenchar & Scott, Chicago, Ill., for plaintiffs-appellants.

George C. Lombardi, Bradley C. Graveline, Michael K. Nutter, Eric L. Broxterman, and William P. Ferranti, of Winston & Strawn, Chicago, for defendant-appellee.

Intellectual Property Library ISSN 1526-8535

Judge

Before Newman, Friedman, and Mayer, circuit judges.

Opinion Text

Opinion By:

Mayer, J.

Bayer Schering Pharma AG ("Bayer") appeals the judgment of the United States District Court for the District of New Jersey, holding U.S. Patent No. 6,787,531 ("'531 Patent") invalid due to obviousness. Bayer Schering Pharma AG v. Barr Labs., Inc., No. 05-CV-2308 (D.N.J March 3, 2008). Because we hold that the invention would have been obvious to try, we affirm.

BACKGROUND

Bayer is a large pharmaceutical company that produces the daily oral contraceptive, Yasmin®. One of the active ingredients in Yasmin, drospirenone, is a progestin that inhibits ovulation. Each of the invalidated claims requires

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drospirenone as the active ingredient. Drospirenone was known in the art at all times relevant. Its contraceptive qualities are particularly well suited for producing an oral contraceptive because, in addition to inhibiting ovulation, it is a diuretic which will diminish excess water retention arising from the estrogen component of oral contraceptives, and has anti-acne qualities to promote clear skin. These desirable qualities have led to Yasmin's success. Drospirenone is also acid-sensitive. When exposed to low-pH (highly acidic) environments such as found in the human stomach, drospirenone "isomerizes" - that is, the acid catalyzes a reaction that rearranges drospirenone's molecular structure while its molecular composition remains constant. The resulting isomer is non-antimineral ocorticoidal, meaning it will not act as a diuretic, removing the desirable anti-bloating effect that sets drospirenone apart from other prior art progestins. Therefore, scientists working with drospirenone for use in an oral contraceptive must be aware of and work around the effects that the human stomach will have on the drug to ensure that its "bioavailability" — the amount of the active drug absorbed into the bloodstream and available to act on the body — is high enough to perform its contraceptive function.

Drospirenone is also a poorly water soluble hydrophobic composition. Because it will not easily dissolve into a volume of liquid, its bioavailability is degraded. To combat this, pharmaceutical producers commonly employ a technique called "micronization," whereby the drug's particle size is reduced, increasing its overall surface area. Often(but not always) with a larger surface area, the dissolution rate is also increased, ensuring that all of the poorly water soluble drug that can dissolve will dissolve in a given volume of liquid. With more of the drug dissolved, the drug will exhibit a higher bioavailability. Indeed, Bayer's expert testified at trial that this would be his first choice in attempting to increase the dissolution rate because, among the different ways to increase the dissolution rate, micronization presents the best chance of success. All commercially available oral contraceptives use micronized progestins and/or estrogens, so this technique was well known in the art.

While micronizing a poorly water soluble composition may result in increased bioavailability, micronizing an acid-sensitive composition may also increase its sensitivity to the acid. A drug that isomerizes when exposed to acid thus may isomerize at a faster rate if it is micronized.

One method pharmaceutical companies use to surmount an acid-sensitivity problem with a drug to be taken orally is to deliver the drug via an enteric-coated pill, as opposed to an immediate release pill, also called a "normal pill." An enteric coating is a pH-sensitive film that protects the drug from stomach acid,

and only releases the drug when it has passed into the less acidic duodenum and small intestine. However, enteric coatings are not without drawbacks themselves. Coated tablets including enteric coated tablets present an obstacle to absorption, and thus reduce the drug's exhibited bioavailability. Additionally, as was known in the art at the time, they introduce a significant delay in the onset of therapeutic response while creating a considerable patient-to-patient variation of that onset. In fact, even for an individual taking the drug at different times, the response time may vary considerably from dose to dose. Bayer scientists noticed these intra- and inter-individual bioavailability differences in practice in their studies on beagles and women. This presented a further complication because Bayer required the drug to be 99% effective, and work on all women at a single dose — "one dose must fit all." A normal pill may not present such variations, but will expose its contents to the stomach's highly acidic environment.

Dr. Johannes Tack, a Bayer scientist, began work in 1983 to develop drospirenone into an oral contraceptive. At the time, Bayer had been working with a related compound, spirorenone, as a diuretic. When consumed, spirorenone metabolizes into drospirenone, which is still a diuretic, but was found to have progestogenic (contraceptive) effects. Spirorenone itself had some contraceptive effects that Bayer concluded were the result of the appearance of drospirenone when it metabolized. Bayer decided to harness the diuretic effect of isolated drospirenone to create the new contraceptive. Tack consulted prior Bayer work with drospirenone including in vitro isomerization studies performed by a fellow Bayer scientist, Dr. Werner Krause. Krause had also performed in vivo studies with spirorenone, about which he published three articles. These studies, Krause I, II, and III, included the knowledge that drospirenone was a

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metabolite of spirorenone. Tack decided, however, that these in vivo studies garnered little information on the practice of drospirenone in vivo.

Tack tested the stability of drospirenone in acid at pH 1 to simulate the conditions of the stomach. He found that after 10 minutes, 21% of the drospirenone had isomerized in the acid, and after 45 minutes, half had isomerized. He came to a critical conclusion:

If the results obtained in vitro are applied to in vivo conditions, it can be presumed that, with an assumed gastric juice volume of 100ml, the majority of the dose (solubility of drospirenone 5-10 mg/l) passes into solution during passage through the stomach and consequently undergoes rapid isomerization. A clear reduction in the bioavailability of the unchanged active substance is to be expected as a result.

The planned studies on the progestogenic efficacy of [drospirenone] should therefore be performed with an enteric-coated formulation.

Tack then moved into clinical studies with an enteric-coated formulation of drospirenone. For five years, Bayer used this coated pill in its studies, even reconfirming in 1988 that drospirenone needed an enteric coating because it isomerized quickly in a pH 1 acidic solution.

In 1988, Bayer also planned a study to determine how effectively its enteric-coated tablet delivered a formulation as compared to an intravenous injection of the same formulation. This study would thus measure the "absolute bioavailability" of the drug. Bayer added what it terms a "non-routine" element to the study, by which it added an unprotected (normal) drospirenone tablet and compared its bioavailability to that of the enteric-coated formulation and the intravenous delivery. Tack expected to find that the enteric-coated tablet would produce a lower bioavailability than an intravenous injection, while the normal pill would produce an even lower bioavailability than the enteric-coated tablet. However, he found that despite his observations that drospirenone would quickly isomerize in a highly acidic environment and his belief therefore that an enteric coating would be necessary to preserve bioavailability, the normal pill and the enteric-coated pill resulted in the same bioavailability. Following this study, Bayer developed drospirenone in a normal pill, for which it would eventually receive the '531 patent.

Bayer relied on the finding that drospirenone would absorb with a normal pill to overcome an obviousness rejection in the Patent and Trademark Office. During prosecution, the examiner rejected the claims as obvious in view of a De Castro reference, which the examiner said taught to micronize poorly soluble drugs to increase their bioavailability. Bayer responded that another piece of prior art, the Nickisch reference, taught that micronizing drospirenone would increase its exposure to the highly acidic environment in the stomach, which would result in increased isomerization. The examiner allowed the claims, giving the specific reason that the prior art suggested that micronizing drospirenone would not work: "The micronized drospirenone will be degraded even more rapidly because the micronization of drospirenone expose[sic] the drug particles in the stomach (acidic). Therefore, to formulate an oral dosage forms [sic] containing the drospirenone particles, which exposed to the gastric environment upon dissolution, would be un[o]bvious in view of the data presented'

The '531 patent issued on September 7, 2004. Claim 1 is representative:

1. A pharmaceutical composition comprising from about 2 mg to about 4 mg of micronized drospirenone particles, about 0.01 mg to about 0.05 mg of 17.alpha.-ethinylestradiol, and one or more pharmaceutically acceptable carriers,

the composition being in an oral dose form exposed to the gastric environment upon dissolution,

and the composition being effective for oral contraception in a human female.

Barr Laboratories ("Barr") makes generic pharmaceuticals, and filed an Abbreviated New Drug Application with the Food and Drug Administration seeking approval to market a generic version of Yasmin®. Bayer promptly filed a patent infringement suit against Barr. The parties agreed that if the '531 patent is valid, Barr infringes claims 1, 5, 8, 27, 29, 36, 49, and 50. Barr then alleged that these claims are obvious, among other invalidity and unenforceability arguments. At

Page 1572

trial, the two parties agreed that 2-4 mg drospirenone was well known in the art, as well as its combination with 0.01-0.05 mg 17á-ethinylestradiol, a pharmaceutically acceptable carrier, and a kit containing 21 such tablets with active ingredients and 7 placebos, to be used as an effective oral contraceptive in human females. Bayer claimed that its innovation was that the drospirenone could be micronized to increase its bioavailability, and that the micronized drospirenone would not need to be enteric coated for protection against the highly acidic gastric environment.

The district court ruled that these claims were invalid as obvious, and rejected Barr's other theories. The court found that a person having ordinary skill in the art would have considered the Krause I, II, and III studies' results that spirorenone though acid-sensitive would nevertheless absorb in vivo because drospirenone is closely related to spirorenone. It also found that while the Nickisch reference did teach that drospirenone isomerizes in vitro when exposed to acid simulating the human stomach, a person of ordinary skill would be aware of the study's shortcomings, and would verify whether drospirenone absorbed or isomerized with precise in vivo and in vitro testing as suggested by the Robert Aulton treatise, Pharmaceutrics: The Science of Dosage Form Design (1988). It then held that under KSR International Co. v. Teleflex Inc., 550 U.S. 398 [82 USPQ2d 1385] (2007), it would have been obvious to a person having ordinary skill in pharmaceutical formulation to try a normal pill in formulating drospirenone as an oral contraceptive. Bayer timely appeals this ruling; Barr does not cross-appeal its adverse rulings. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

Obviousness under 35 U.S.C. § 103 is the sole issue in this appeal. Whether an invention would have been obvious at the time the invention was made is a question of law, which we review de novo, based on underlying facts, which we review for clear error. Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1355 [83 USPQ2d 1169](Fed. Cir. 2007). A district court's finding is clearly erroneous Copyright 2010, The Bureau of National Affairs, Inc.

when, despite some supporting evidence, we are "left with the definite and firm conviction that a mistake has been committed." Forest Labs., Inc. v. Abbott Labs., 339 F.3d 1324, 1328 [67 USPQ2d 1682] (Fed. Cir. 2003) (quoting United States v. U.S. Gypsum Co., 333 U.S. 364, 395 [76 USPQ 430] (1948)).

A patent may not be obtained if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. § 103(a). An obviousness analysis is based on several factual inquiries. A court must examine the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art. Graham v. John Deere Co., 383 U.S. 1, 17-18 [148 USPQ 459] (1966). At that point, a court may consider secondary objective evidence of non-obviousness, such as commercial success, long felt but unsolved need, failure of others, and the like. Id.

In KSR, the Supreme Court stated that an invention may be found obvious if it would have been obvious to a person having ordinary skill to try a course of conduct:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

550 U.S. at 421. This approach is consistent with our methodology in In re O'Farrell, 853 F.2d 894 [7 USPQ2d 1673] (Fed. Cir. 1988). See Procter & Gamble Co. v Teva Pharms. USA, Inc., 566 F.3d 989, 996-97 [90 USPQ2d 1947] (Fed. Cir. 2009); In re Kubin, 561 F.3d 1351, 1359 [90 USPQ2d 1417], (Fed. Cir. 2009). O'Farrell observed that most inventions that are obvious were also obvious to try, but found two classes where that rule of thumb did not obtain.

First, an invention would not have been obvious to try when the inventor would have had to try all possibilities in a field unreduced by direction of the prior art. When "what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at

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a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful" an invention would not have been obvious. O'Farrell, 853 F.2d at 903. This is another way to express the KSR prong requiring the field of search to be among a "finite number of identified" solutions. 550 U.S. at 421; see also Procter & Gamble, 566 F.3d at 996; Kubin, 561 F.3d at 1359. It is also consistent with our interpretation that KSR requires the number of options to be "small or easily traversed." Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1364 [86 USPQ2d 1196] (Fed. Cir. 2008).

Second, an invention is not obvious to try where vague prior art does not guide an inventor toward a particular solution. A finding of obviousness would not obtain where "what was 'obvious to try'was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." O'Farrell, 853 F.2d at 903. This expresses the same idea as the KSR requirement that the identified solutions be "predictable." 550 U.S. at 421; see also Procter & Gamble, 566 F.3d at 996-97; Kubin, 561 F.3d at 1359-60.

Because the use of drospirenone with 17α -ethinylestradiol as an oral contraceptive was known prior art, Bayer represented that the innovation was to micronize the drospirenone to increase its bioavailability, and that the micronized drospirenone would absorb with a normal pill, against the teachings of the prior art. The district court analyzed the prior art and determined that micronizing drospirenone was taught, and that using a normal pill would have been obvious to try.

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The court first determined how the person having ordinary skill in the art of pharmaceutical formulation would consider the correlation of in vitro and in vivo tests. It relied principally on Robert Aulton's pharmacologist textbook, Pharmaceutics: The Science of Dosage Form Design, which, as the court found, teaches that "dissolution rate data when combined with solubility ... provide an insight to the formulator into the potential in vivo absorption characteristics of a drug. However, in vitro tests only have significance if they can be related to in vivo results. Once such a relationship has been established, in vitro dissolution tests can be used as a quality control test. (Aulton, p. 9)." The court concluded that the person of ordinary skill would not accept in vitro testing as valid without a correlation to in vivo tests.

With that knowledge, the court then turned to micronization. It found that Aulton cut both ways on this point, because it taught both that micronizing a poorly water soluble substance like drospirenone may increase its absorption rate, but may also increase the rate of degradation. However, Aulton stated, and other evidence corroborated, that "it is now generally recognized that poorly soluble drugs showing a dissolution rate limiting step in the absorption process will be more readily bioavailable when administered in a finely subdivided [micronized] form with larger surfaces than as the coarse material.... The fine material often in micronized form with larger specific surface dissolves at faster rates which can lead to improved drug absorption by passive diffusion." The district court acknowledged that the prior art suggested that there would be concern about the dissolution of a poorly water soluble acid-sensitive drug, but found that the prior art generally suggests that micronization could improve the dissolution of drospirenone. It concluded that a person having ordinary skill would have seen it as a viable option.

Bayer argues that this is clear error because the court relied on one piece of prior art to show that micronization has been shown to work on acid-sensitive compounds. The court reviewed the Hargrove reference, which was a study on micronizing progesterone, concluding that "it confirms that not all acidsensitive drugs require enteric coating."This is incorrect, as Barr agrees, because progesterone is not an acid-sensitive drug. However, Bayer's own expert, Dr. James McGinity, testified that micronization is the first choice solution because it presents the best chance for success. So there remains adequate support for the conclusion that micronization was a viable option.

The district court then moved to Bayer's second alleged non-obvious aspect of the invention, whether the formulation should use an enteric-coated or normal tablet delivery. The court considered Bayer's argument that prior art taught formulation scientists to employ an enteric coating on drospirenone, and

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Barr's argument that an enteric coating is so complicated, expensive, cumbersome to manufacture, and prone to variability that it only would be used as a last resort by formulation scientists working with an acid-sensitive drug. The court found neither side persuasive, and considered the prior art as the center, again focusing on the Aulton textbook. It found that Aulton recognizes the necessity of an enteric coating to the formulation of acid-sensitive drugs, but that an enteric coating also introduces drawbacks, including that enteric coated tablets have the lowest bioavailability of all drug delivery forms. Poor bioavailability of drospirenone is the major problem that Tack sought to solve. The district court further found that Aulton teaches that there is variability in bioavailability both intra- and inter-subject when using enteric coated tablets, which is a significant obstacle to Bayer's requirement that the drug must be 99% effective for all women.

In effect, while Bayer argued that prior art teaches away from using micronized drospirenone in a normal tablet, Barr argued that the prior art teaches away from using an enteric coating. What the parties have done, however, is present the options available to a pharmaceutical formulator having ordinary skill to solve the problem of acid-sensitive but hydrophobic drospirenone.

Barr argued that the Krause series on spirorenone is controlling because of the great similarity between spirorenone and drospirenone. The Krause series tested the bioavailability of spirorenone in vivo in humans and monkeys to determine whether there was need to develop a "pharmaceutical formulation resistant to gastric juice."The studies each found no spirorenone isomers in the subjects' blood streams, Copyright 2010, The Bureau of National Affairs, Inc.

and concluded that spirorenone is absorbed before it isomerizes. Furthermore, an in vitro comparison found that drospirenone isomerized in pH 1 acid with a profile similar to spirorenone. The court found that the drugs were closely related in that they are both (1) acid-sensitive at similar rates, (2) steroids having the same pharmacological properties,(3) derivatives of the same drug, (4) of the same chemical composition except for one bond, and (5) from the same family of substances. The court then concluded that a person of ordinary skill would find the drugs closely related, and would therefore access these studies when formulating drospirenone. He would be led to believe that drospirenone, like spirorenone, may absorb in vivo, but isomerize in vitro.

Bayer argues now that the district court ignored key differences between drospirenone and spirorenone, such as that the former isomerizes 40% faster than the latter, and that drospirenone is more soluble and thus could dissolve and isomerize in acid faster. This is irrelevant because the Krause series prior art is not an anticipatory reference. It can be used to show that a drug formulator having ordinary skill had a viable known option to consider with micronized, unprotected drospirenone, and a reasonable expectation that drospirenone would perform similarly (even if not identically) to the spirorenone in the Krause series. See O'Farrell, 853 F.2d at 903-904("Obviousness does not require absolute predictability of success ...all that is required is a reasonable expectation of success.").

Similarly, Bayer argued that the Nickisch article teaches that drospirenone isomerizes when exposed to acid in vitro, teaching away from allowing exposure to the gastric environment, and thus suggesting the need for an enteric coating. Barr attacked the merits of the study as it would apply to the practice of drospirenone in vivo, noting that Nickisch did not test drospirenone in vivo to correlate its in vitro findings. Barr also challenged the Nickisch reference on the grounds that drospirenone was found to isomerize slowly and would not have isomerized before the stomach emptied, that the in vitro environment was too extreme to be compared to an in vivo practice, and that it did not explain its testing protocols. The court found that a person of ordinary skill in the art would recognize that Nickisch establishes that drospirenone isomerizes in vitro, but would be alerted to the study's shortcomings when used in vivo.

[1] At this point, a person having ordinary skill in the art has reached a crossroads where he must choose between two known options: delivery of micronized drospirenone by a normal pill following the spirorenone analogy in the Krause series, or delivery of drospirenone by an enteric-coated pill following the Nickisch teaching that the drug needs to be protected from the stomach. This is a finite number of identified, predictable solutions. See KSR. 550 U.S. at 421. The prior art would have funneled the formulator toward these two options; he would not have been required

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to try all possibilities in a field unreduced by the prior art, thus avoiding the first pitfall of *O'Farrell*, 853 F.2d at 903. Additionally, the prior art was not vague in pointing toward a general approach or area of exploration, but rather guided the formulator precisely to the use of either a normal pill or an enteric-coated pill, thus avoiding the second pitfall of *O'Farrell*. *Id*. Because the selection of micronized drospirenone in a normal pill led to the result anticipated by the Krause series, the invention would have been obvious. *See KSR*, 550 U.S. at 421.

CONCLUSION

Accordingly, the judgment of the United States District Court for the District of New Jersey is affirmed.

AFFIRMED

Dissenting Opinion Text

Dissent By:

Newman, J., dissenting.

With all respect to my colleagues, I do not share their view that it would have been obvious to do that which was indisputably unobvious to the experienced formulation scientists whose assignment was to formulate the known product drospirenone. The evidence showed, without contradiction, that it was known that micronized drospirenone rapidly degraded at the acidity of stomach acid. The evidence showed, without contradiction, that the Bayer scientists working in this field believed that the product required an enteric coating in order to prevent degradation in the stomach, upon ingestion as an oral contraceptive. Yet my colleagues, employing their own expertise, hold that since the scientists working in this field turned out to be mistaken, it would have been obvious that it was not necessary to take steps to prevent acid degradation. The court discounts the testimony of the scientists themselves, ignores the knowledge concerning this product and its instability in acid, ignores the textbook teachings, and finds that this unlikely process obviously should have been tried. That is not the law of obviousness.

The statutory criterion is whether the invention would have been obvious to persons of ordinary skill at the time of the invention, not whether it is sufficiently simple to appear obvious to judges after the discovery is finally made, despite the years of contrary belief among the scientists charged with the project. At the time that the Bayer scientists were attempting to formulate drospirenone as an oral contraceptive, the textbook teaching was that micronizing acid-sensitive products would accelerate their acid-induced degradation. See, e.g., Aulton's Pharmaceutics: The Design and Manufacture of Medicines (advising against micronizing acid-sensitive drugs because it reduces the drug's bioavailability). My colleagues criticize these specialists, and rule that it was nonetheless obvious to conduct experiments that they believed would not work. The court rules that the scientists should have "tried" that which they believed would fail, and that when they eventually did try this unlikely formulation, and it succeeded, it was obvious to do so.

The unusual physiological behavior of drospirenone in the stomach was not known; this knowledge followed as scientific explanation; it did not precede the invention in suit. There was no evidence to reasonably suggest that micronized drospirenone was likely to be usable, with 99+ percent consistency of effectiveness, without any protection from degradation by stomach acid. A usable contraceptive requires virtually complete effectiveness, and the standard confronting the Bayer scientists was high. Unlike the unrelated drugs cited by the panel majority, contraceptives require complete effectiveness. Previously known oral contraceptives such as progesterone and spironolactone are not acid sensitive, and drospirenone presented a highly specific challenge to the formulation scientists. The Bayer scientists believed that the way of avoiding the known acid degradation of drospirenone was to protect it from acid. My colleagues, however, find that it would have been obvious to expose it to acid, although it was not obvious to the scientists working on the project.

"Obviousness" requires that the subject matter was obvious to persons of ordinary skill in the field of the invention. The law does not hold it "obvious to try" experiments that contravene conventional knowledge, and that are not deemed reasonably likely to succeed. The evidence in this case is a better measure of obviousness than is the hindsight science of judges, for the scientists who eventually made this discovery testified, without dispute, that they did not believe an uncoated micronized product would meet the demanding criteria of contraceptive effectiveness. The Court in KSR

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International Co. v. Teleflex Inc., 550 U.S. 398 [82 USPQ2d 1385] (2007) explained that the standard for "obvious to try" is whether there was a "reasonable expectation of success" at the time. It was undisputed that there was not. It was undisputed that it was not reasonably expected that uncoated micronized drospirenone would be 99+% effective as an oral contraceptive when ingested into the acidic stomach, when it was known to degrade rapidly in acid.

The district court stated that micronization was a "viable" option, and that although success was "uncertain," the invention was obvious to try. However, "viability" is not the standard. "Viability" implies that the experiment may or may not succeed. What the law requires is not guesswork, not dumb luck, but a reasonable degree of predictability of success. My colleagues depart from the statutory standard, in ruling Copyright 2010, The Bureau of National Affairs, Inc.

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that persons of ordinary skill would have conducted experiments that were expected to fail. Nothing in the prior art teaches the likelihood of success of ingestion of uncoated micronized drospirenone; what is taught is the likelihood of failure.

The invention must be viewed as a whole. With the existing knowledge that drospirenone is both hydrophobic and that it degrades rapidly in acid, and the existing knowledge that micronization, although useful to counteract a drug's hydrophobic properties, renders the drug even more susceptible to acid degradation, it was not shown that a person of ordinary skill in this field would have had a reasonable expectation of achieving complete contraceptive bioavailability and effectiveness with uncoated micronized drospirenone. The contrary view has surfaced only in this litigation-induced argument. The exercise of judicial expertise to override the clear evidence of how persons of skill in this field actually behaved, is inappropriate.

I respectfully dissent.

- End of Case -

5. KSR International Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007).

Source: USPQ, 2d Series (1986 - Present) > U.S. Supreme Court > KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)

KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)

82 USPQ2d 1385
KSR International Co. v. Teleflex Inc.
U.S. Supreme Court
No. 04-1350
Decided April 30, 2007
127 SCt 1727
167 LEd2d 705
550 US 398

Headnotes

PATENTS

[1] Patentability/Validity — Obviousness — Combining references (>115.0905)

Rigid application of "teaching, suggestion, or motivation" test, under which patent claim is proved obvious only if prior art, nature of problem addressed by inventor, or knowledge of person having ordinary skill in art reveals some motivation or suggestion to combine prior art teachings, is inconsistent with expansive and flexible "functional approach" to resolution of obviousness issue, under which scope and content of prior art are determined, differences between prior art and claims at issue are ascertained, level of ordinary skill in pertinent art is resolved, and secondary considerations such as commercial success, long felt but unsolved needs, and failure of others may be considered if doing so would prove instructive; rigid TSM approach is therefore rejected.

[2] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Patentability/Validity — Obviousness — Evidence of (▶115.0906)

Variations of particular work available in one field of endeavor may be prompted by design incentives and other market forces, either in same field or different one, and if person of ordinary skill in art can implement predictable variation, 35 U.S.C. § 103 likely bars its patentability; similarly, if particular technique has been used to improve one device, and person of ordinary skill would recognize that it would improve similar devices in same way, then using that technique is obvious unless its actual application is beyond person's skill, and court resolving obviousness issue therefore must ask whether improvement is more than predictable use of prior art elements according to their established functions.

[3] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Patentability/Validity — Obviousness — Evidence of (▶115.0906)

Court determining whether claimed combination of elements known in prior art would have been obvious will often be required to look to interrelated teachings of multiple patents, effects of demands known to design community or present in marketplace, and background knowledge of person of ordinary skill in art in order to determine whether there was apparent reason to combine known elements in manner claimed in patent in suit, and in order to facilitate review, this analysis should be made explicit; however, such analysis need not seek out precise teachings directed to specific subject matter of challenged claim, since court can take account of inferences and creative steps that person of ordinary skill in art would employ.

[4] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Idea underlying "teaching, suggestion, or motivation" test, under which patent claim is proved obvious only if prior art, nature of problem addressed by inventor, or knowledge of person having ordinary skill in art reveals some motivation or suggestion to combine prior art teachings, is not necessarily inconsistent with expansive and flexible "functional approach" to resolution of obviousness issue, since TSM test is based on helpful insights, namely, that patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in prior art, and that it can be important to identify reason that would have prompted person of ordinary skill in art to combine elements in manner claimed by new invention; however, it is error to apply TSM test as rigid and mandatory formula that limits obviousness analysis through formalistic conception of words "teaching," "suggestion," and "motivation," or by overemphasis on importance of published articles and explicit content of issued patents, since market demand, rather than scientific literature, often drives design trends, and granting patent protection to advances that would occur "in the ordinary course" without real innovation retards progress and may, in case of patents

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combining previously known elements, deprive prior inventions of their value or utility.

[5] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Narrow conception of obviousness inquiry, reflected in appellate court's application of "teaching, suggestion, or motivation" test, resulted in erroneous conclusion that summary judgment of obviousness should be vacated, since decision was based on erroneous holding that courts and patent examiners should look only to problem that patentee was trying to solve, and on erroneous assumption that person of ordinary skill in art attempting to solve problem will be led only to those elements of prior art designed to solve same problem, since court erroneously concluded that patent claim cannot be proved obvious merely by showing that combination of elements was "obvious to try," and since appellate court drew wrong conclusion from risk of courts and patent examiners falling prey to "hindsight" bias, in that rigid application of preventative rules that deny fact finders recourse to common sense are neither necessary nor consistent with precedent.

[6] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Patentability/Validity — Obviousness — Evidence of (▶115.0906)

Fact that claimed combination of elements was "obvious to try" might show that such combination was obvious under 35 U.S.C. § 103, since, if there is design need or market pressure to solve problem, and there are finite number of identified, predictable solutions, person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation.

[7] Patentability/Validity — Obviousness — Relevant prior art — Particular inventions **(▶115.0903.03)**

Patentability/Validity — Obviousness — Combining references (▶115.0905)

Asserted claim of patent for position-adjustable vehicle pedal assembly having electronic pedal-position sensor attached to fixed pivot point is invalid as obvious over combination of prior art references, since prior art patent discloses support structure for adjustable pedal assembly in which one pivot point stays fixed, since, at relevant time, marketplace had created strong incentive to convert mechanical pedals to those employing electronic sensors, and pedal designer of ordinary skill would have seen benefit in upgrading device of prior patent with sensor required by new engines using computer-controlled throttles, since other prior art references taught utility of placing sensor on pedal's support structure rather than on footpad, and on nonmoving part of pedal structure, since most obvious nonmoving point on structure from Copyright 2010, The Bureau of National Affairs, Inc.

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which sensor can easily detect pedal position is fixed pivot point, and since designer seeking to avoid wire-chafing problems with electronic adjustable pedals would have known to employ adjustable pedal with fixed pivot disclosed by prior art patent; declaration submitted by patentees does not indicate that device of prior patent was so flawed that there was no reason to upgrade it to be compatible with modern engines, and patentees have shown no secondary considerations to dislodge obviousness determination.

[8] Patentability/Validity — Obviousness — Evidence of (▶115.0906)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Summary judgment — Patents (▶410.3303)

Procedure — Evidence — Expert testimony (▶410.3703)

Party's submission of conclusory expert affidavit addressing issue of obviousness in patent action does not preclude summary judgment, even though federal district court can and should take into account expert testimony, which may resolve or keep open certain questions of fact, since ultimate judgment of obviousness is legal determination; in present case, in which content of prior art, scope of asserted claim, and level of ordinary skill in art were not in material dispute, and obviousness of claim was apparent from these factors, summary judgment was appropriate, and nothing in declarations proffered by patentees prevented district court from reaching conclusions underlying its order for summary judgment of obviousness.

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Particular Patents

Particular patents — General and mechanical —Vehicle control pedal assembly

6,237,565, Engelgau, adjustable pedal assembly with electronic throttle control, invalid for obviousness.

Case History and Disposition

On writ of certiorari to the U.S. Court of Appeals for the Federal Circuit, Schall, J.

Action by Teleflex Inc. and Technology Holding Co. against KSR International Co. for patent infringement. The U.S. District Court for the Eastern District of Michigan granted summary judgment in favor of defendant on ground that patent in suit was invalid for obviousness, and plaintiffs appealed. Grant of summary judgment was vacated and remanded, and defendant-appellee filed petition for writ of certiorari. Reversed and remanded.

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Syllabus

Syllabus by the Court.

To control a conventional automobile's speed, the driver depresses or releases the gas pedal, which interacts with the throttle via a cable or other mechanical link. Because the pedal's position in the footwell normally cannot be adjusted, a driver wishing to be closer or farther from it must either reposition himself in the seat or move the seat, both of which can be imperfect solutions for smaller drivers in cars with deep footwells. This prompted inventors to design and patent pedals that could be adjusted to change their locations. The Asano patent reveals a support structure whereby, when the pedal location is adjusted, one of the pedal's pivot points stays fixed. Asano is also designed so that the force necessary to depress the pedal is the same regardless of location adjustments. The Redding patent reveals a different, sliding mechanism where both the pedal and the pivot point are adjusted.

In newer cars, computer-controlled throttles do not operate through force transferred from the pedal by a mechanical link, but open and close valves in response to electronic signals. For the computer to know what is happening with the pedal, an electronic sensor must translate the mechanical operation into digital data. Inventors had obtained a number of patents for such sensors. The so-called '936 patent taught that it was preferable to detect the pedal's position in the pedal mechanism, not in the engine, so the patent disclosed a pedal with an electronic sensor on a pivot point in the pedal assembly. The Smith patent taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's footpad. Inventors had also patented self-contained modular sensors, which can be taken off the shelf and attached to any mechanical pedal to allow it to function with a computer-controlled throttle. The '068 patent disclosed one such sensor. Chevrolet also manufactured trucks using modular sensors attached to the pedal support bracket, adjacent to the pedal and engaged with the pivot shaft about which the pedal rotates. Other patents disclose electronic sensors attached to adjustable pedal assemblies. For example, the Rixon patent locates the sensor in the pedal footpad, but is known for wire chafing.

After petitioner KSR developed an adjustable pedal system for cars with cable-actuated throttles and obtained its '976 patent for the design, General Motors Corporation (GMC) chose KSR to supply adjustable pedal systems for trucks using computer-controlled throttles. To make the '976 pedal compatible with the trucks, KSR added a modular sensor to its design. Respondents (Teleflex) hold the exclusive license for the Engelgau patent, claim 4 of which discloses a position-adjustable pedal assembly with an electronic pedal position sensor attached at a fixed pivot point. Despite having denied a similar, broader claim, the

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U.S. Patent and Trademark Office (PTO) had allowed claim 4 because it included the limitation of a fixed pivot position, which distinguished the design from Redding's. Asano was neither included among the Engelgau patent's prior art references nor mentioned in the patent's prosecution, and the PTO did not have before it an adjustable pedal with a fixed pivot point. After learning of KSR's design for GMC, Teleflex sued for infringement, asserting that KSR's pedal system infringed the Engelgau patent's claim 4. KSR countered that claim 4 was invalid under § 103 of the Patent Act, which forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art."

Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17–18 [148 USPQ 459], set out an objective analysis for applying § 103: "[T]he scope and content of the prior art are ... determined; differences between the prior art and the claims at issue are ... ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs,

failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." While the sequence of these questions might be reordered in any particular case, the factors define the controlling inquiry. However, seeking to resolve the obviousness question with more uniformity and consistency, the Federal Circuit has employed a "teaching, suggestion, or motivation" (TSM) test, under which a patent claim is only proved obvious if the prior art, the problem's nature, or the knowledge of a person having ordinary skill in the art reveals some motivation or suggestion to combine the prior art teachings.

The District Court granted KSR summary judgment. After reviewing pedal design history, the Engelgau patent's scope, and the relevant prior art, the court considered claim 4's validity, applying Graham's framework to determine whether under summary-judgment standards KSR had demonstrated that claim 4 was obvious. The court found "little difference" between the prior art's teachings and claim 4: Asano taught everything contained in the claim except using a sensor to detect the pedal's position and transmit it to a computer controlling the throttle. That additional aspect was revealed in, e.g., the '068 patent and Chevrolet's sensors. The court then held that KSR satisfied the TSM test, reasoning (1) the state of the industry would lead inevitably to combinations of electronic sensors and adjustable pedals, (2) Rixon provided the basis for these developments, and (3)Smith taught a solution to Rixon's chafing problems by positioning the sensor on the pedal's fixed structure, which could lead to the combination of a pedal like Asano with a pedal position sensor.

Reversing, the Federal Circuit ruled the District Court had not applied the TSM test strictly enough, having failed to make findings as to the specific understanding or principle within a skilled artisan's knowledge that would have motivated one with no knowledge of the invention to attach an electronic control to the Asano assembly's support bracket. The Court of Appeals held that the District Court's recourse to the nature of the problem to be solved was insufficient because, unless the prior art references addressed the precise problem that the patentee was trying to solve, the problem would not motivate an inventor to look at those references. The appeals court found that the Asano pedal was designed to ensure that the force required to depress the pedal is the same no matter how the pedal is adjusted, whereas Engelgau sought to provide a simpler, smaller, cheaper adjustable electronic pedal. The Rixon pedal, said the court, suffered from chafing but was not designed to solve that problem and taught nothing helpful to Engelgau's purpose. Smith, in turn, did not relate to adjustable pedals and did not necessarily go to the issue of motivation to attach the electronic control on the pedal assembly's support bracket. So interpreted, the court held, the patents would not have led a person of ordinary skill to put a sensor on an Asano-like pedal. That it might have been obvious to try that combination was likewise irrelevant. Finally, the court held that genuine issues of material fact precluded summary judgment.

Held: The Federal Circuit addressed the obviousness question in a narrow, rigid manner that is inconsistent with § 103 and this Court's precedents. KSR provided convincing evidence that mounting an available sensor on a

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fixed pivot point of the Asano pedal was a design step well within the grasp of a person of ordinary skill in the relevant art and that the benefit of doing so would be obvious. Its arguments, and the record, demonstrate that the Engelgau patent's claim 4 is obvious. Pp. 11–24.

1. Graham provided an expansive and flexible approach to the obviousness question that is inconsistent with the way the Federal Circuit applied its TSM test here. Neither § 103's enactment nor Graham's analysis disturbed the Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art. See Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152 [87 USPQ 303]. Such a combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See, e.g., United States v. Adams, 383 U.S. 39, 50-52 [148 USPQ 479]. When a work is available in one field, design incentives and other market forces can prompt variations of it, either in the same field or in another. If a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, § 103 likely bars its patentability. Moreover, if a technique has been Copyright 2010, The Bureau of National Affairs, Inc.

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used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions. Following these principles may be difficult if the claimed subject matter involves more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ. Pp. 11-14.

(b) The TSM test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. Although common sense directs caution as to a patent application claiming as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does. Inventions usually rely upon building blocks long since uncovered, and claimed discoveries almost necessarily will be combinations of what, in some sense, is already known. Helpful insights, however, need not become rigid and mandatory formulas. If it is so applied, the TSM test is incompatible with this Court's precedents. The diversity of inventive pursuits and of modern technology counsels against confining the obviousness analysis by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasizing the importance of published articles and the explicit content of issued patents. In many fields there may be little discussion of obvious techniques or combinations, and market demand, rather than scientific literature, may often drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, for patents combining previously known elements, deprive prior inventions of their value or utility. Since the TSM test was devised, the Federal Circuit doubtless has applied it in accord with these principles in many cases. There is no necessary inconsistency between the test and the Graham analysis. But a court errs where, as here, it transforms general principle into a rigid rule limiting the obviousness inquiry. Pp. 14-15.

(c)The flaws in the Federal Circuit's analysis relate mostly to its narrow conception of the obviousness inquiry consequent in its application of the TSM test. The Circuit first erred in holding that courts and patent examiners should look only to the problem the patentee was trying to solve. Under the correct analysis, any need or problem known in the field and addressed by the patent can provide a reason for combining the elements in the

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manner claimed. Second, the appeals court erred in assuming that a person of ordinary skill in the art attempting to solve a problem will be led only to those prior art elements designed to solve the same problem. The court wrongly concluded that because Asano's primary purpose was solving the constant ratio problem, an inventor considering how to put a sensor on an adjustable pedal would have no reason to consider putting it on the Asano pedal. It is common sense that familiar items may have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle. Regardless of Asano's primary purpose, it provided an obvious example of an adjustable pedal with a fixed pivot point, and the prior art was replete with patents indicating that such a point was an ideal mount for a sensor. Third, the court erred in concluding that a patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try. When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. Finally, the court drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. Rigid preventative Copyright 2010, The Bureau of National Affairs, Inc.

rules that deny recourse to common sense are neither necessary under, nor consistent with, this Court's case law. Pp. 15–18.

- 2. Application of the foregoing standards demonstrates that claim 4 is obvious. Pp. 18–23.
- (a)The Court rejects Teleflex's argument that the Asano pivot mechanism's design prevents its combination with a sensor in the manner claim 4 describes. This argument was not raised before the District Court, and it is unclear whether it was raised before the Federal Circuit. Given the significance of the District Court's finding that combining Asano with a pivot-mounted pedal position sensor fell within claim 4's scope, it is apparent that Teleflex would have made clearer challenges if it intended to preserve this claim. Its failure to clearly raise the argument, and the appeals court's silence on the issue, lead this Court to accept the District Court's conclusion. Pp. 18–20.
- (b)The District Court correctly concluded that when Engelgau designed the claim 4 subject matter, it was obvious to a person of ordinary skill in the art to combine Asano with a pivot-mounted pedal position sensor. There then was a marketplace creating a strong incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for doing so. The Federal Circuit considered the issue too narrowly by, in effect, asking whether a pedal designer writing on a blank slate would have chosen both Asano and a modular sensor similar to the ones used in the Chevrolet trucks and disclosed in the '068 patent. The proper question was whether a pedal designer of ordinary skill in the art, facing the wide range of needs created by developments in the field, would have seen an obvious benefit to upgrading Asano with a sensor. For such a designer starting with Asano, the question was where to attach the sensor. The '936 patent taught the utility of putting the sensor on the pedal device. Smith, in turn, explained not to put the sensor on the pedal footpad, but instead on the structure. And from Rixon's known wire-chafing problems, and Smith's teaching that the pedal assemblies must not precipitate any motion in the connecting wires, the designer would know to place the sensor on a nonmoving part of the pedal structure. The most obvious such point is a pivot point. The designer. accordingly, would follow Smith in mounting the sensor there. Just as it was possible to begin with the objective to upgrade Asano to work with a computer-controlled throttle, so too was it possible to take an adjustable electronic pedal like Rixon and seek an improvement that would avoid the wire-chafing problem. Teleflex has not shown anything in the prior art that taught away from the use of Asano, nor any secondary factors to dislodge the determination that claim 4 is obvious. Pp. 20-23.
- 3. The Court disagrees with the Federal Circuit's holding that genuine issues of material fact precluded summary judgment. The ultimate judgment of obviousness is a legal determination. *Graham*, 383 U.S., at 17. Where, as here, the prior art's content, the patent claim's scope, and the level of ordinary skill in the art are not in material dispute and the claim's obviousness

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is apparent, summary judgment is appropriate. P. 23.

119 Fed. Appx. 282, reversed and remanded.

Kennedy, J., delivered the opinion for a unanimous Court.

Opinion Text

Opinion By:

Kennedy, J.

Teleflex Incorporated and its subsidiary Technology Holding Company—both referred to here as Teleflex—sued KSR International Company for patent infringement. The patent at issue, United States Patent No. 6,237,565 B1, is entitled "Adjustable Pedal Assembly With Electronic Throttle Control."

Supplemental App. 1. The patentee is Steven J. Engelgau, and the patent is referred to as "the Engelgau patent." Teleflex holds the exclusive license to the patent.

Claim 4 of the Engelgau patent describes a mechanism for combining an electronic sensor with an adjustable automobile pedal so the pedal's position can be transmitted to a computer that controls the throttle in the vehicle's engine. When Teleflex accused KSR of infringing the Engelgau patent by adding an electronic sensor to one of KSR's previously designed pedals, KSR countered that claim 4 was invalid under the Patent Act, 35 U.S.C. § 103, because its subject matter was obvious.

Section 103 forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

In Graham v. John Deere Co. of Kansas City, 383 U.S. 1 [148 USPQ 459] (1966), the Court set out a framework for applying the statutory language of § 103, language itself based on the logic of the earlier decision in Hotchkiss v. Greenwood, 11 How. 248 (1851), and its progeny. See 383 U.S., at 15-17. The analysis is objective:

"Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Id.*, at 17–18.

While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls. If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103.

Seeking to resolve the question of obviousness with more uniformity and consistency, the Court of Appeals for the Federal Circuit has employed an approach referred to by the parties as the "teaching, suggestion, or motivation" test (TSM test), under which a patent claim is only proved obvious if "some motivation or suggestion to combine the prior art teachings" can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art. See, e.g., Al-Site Corp. v. VSI Int'l. Inc., 174 F.3d 1308, 1323-1324 [50 USPQ2d 1161] (CA Fed. 1999). KSR challenges that test, or at least its application in this case. See 119 Fed. Appx. 282, 286-290 (CA Fed. 2005). Because the Court of Appeals addressed the question of obviousness in a manner contrary to § 103 and our precedents, we granted certiorari, 547 U.S. ___ (2006). We now reverse.

I

A

In car engines without computer-controlled throttles, the accelerator pedal interacts with the throttle via cable or other mechanical link. The pedal arm acts as a lever rotating around a pivot point. In a cableactuated throttle control the rotation caused by pushing down the pedal pulls a cable, which in turn pulls open valves in the carburetor or fuel injection unit. The wider the valves open, the more fuel and air are released, causing combustion to increase and the car to accelerate. When the driver takes his foot off the pedal, the opposite occurs as the cable is released and the valves slide closed.

In the 1990's it became more common to install computers in cars to control engine operation. Computercontrolled throttles open and close valves in response to electronic signals, not through force transferred from the pedal by a mechanical link. Constant, delicate

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adjustments of air and fuel mixture are possible. The computer's rapid processing of factors beyond the pedal's position improves fuel efficiency and engine performance.

For a computer-controlled throttle to respond to a driver's operation of the car, the computer must know what is happening with the pedal. A cable or mechanical link does not suffice for this purpose; at some point, an electronic sensor is necessary to translate the mechanical operation into digital data the computer can understand.

Before discussing sensors further we turn to the mechanical design of the pedal itself. In the traditional design a pedal can be pushed down or released but cannot have its position in the footwell adjusted by sliding the pedal forward or back. As a result, a driver who wishes to be closer or farther from the pedal must either reposition himself in the driver's seat or move the seat in some way. In cars with deep footwells these are imperfect solutions for drivers of smaller stature. To solve the problem, inventors, beginning in the 1970's, designed pedals that could be adjusted to change their location in the footwell. Important for this case are two adjustable pedals disclosed in U.S. Patent Nos. 5,010,782 (filed July 28, 1989) (Asano) and 5,460,061(filed Sept. 17, 1993) (Redding). The Asano patent reveals a support structure that houses the pedal so that even when the pedal location is adjusted relative to the driver, one of the pedal's pivot points stays fixed. The pedal is also designed so that the force necessary to push the pedal down is the same regardless of adjustments to its location. The Redding patent reveals a different. sliding mechanism where both the pedal and the pivot point are adjusted.

We return to sensors. Well before Engelgau applied for his challenged patent, some inventors had obtained patents involving electronic pedal sensors for computer-controlled throttles. These inventions, such as the device disclosed in U.S. Patent No. 5,241,936 (filed Sept. 9, 1991) ('936), taught that it was preferable to detect the pedal's position in the pedal assembly, not in the engine. The '936 patent disclosed a pedal with an electronic sensor on a pivot point in the pedal assembly, U.S. Patent No. 5,063,811 (filed July 9, 1990)(Smith) taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, and to avoid grime and damage from the driver's foot, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's footpad.

In addition to patents for pedals with integrated sensors inventors obtained patents for self-contained modular sensors. A modular sensor is designed independently of a given pedal so that it can be taken off the shelf and attached to mechanical pedals of various sorts, enabling the pedals to be used in automobiles with computer-controlled throttles. One such sensor was disclosed in U.S. Patent No. 5,385,068 (filed Dec. 18, 1992) ('068). In 1994, Chevrolet manufactured a line of trucks using modular sensors "attached to the pedal support bracket, adjacent to the pedal and engaged with the pivot shaft about which the pedal rotates in operation." 298 F.Supp.2d 581, 589(ED Mich. 2003).

The prior art contained patents involving the placement of sensors on adjustable pedals as well. For example, U.S. Patent No. 5,819,593(filed Aug. 17, 1995) (Rixon) discloses an adjustable pedal assembly with an electronic sensor for detecting the pedal's position. In the Rixon pedal the sensor is located in the pedal footpad. The Rixon pedal was known to suffer from wire chafing when the pedal was depressed and released.

This short account of pedal and sensor technology leads to the instant case.

В

KSR, a Canadian company, manufactures and supplies auto parts, including pedal systems. Ford Motor Company hired KSR in 1998 to supply an adjustable pedal system for various lines of automobiles with cable-actuated throttle controls. KSR developed an adjustable mechanical pedal for Ford and obtained U.S. Patent No. 6,151,976 (filed July 16, 1999)('976) for the design. In 2000, KSR was chosen by General Motors Corporation (GMC or GM) to supply adjustable pedal systems for Chevrolet and GMC light trucks that used engines with computer-controlled throttles. To make the '976 pedal compatible with the trucks. Copyright 2010, The Bureau of National Affairs, Inc.

KSR merely took that design and added a modular sensor.

Teleflex is a rival to KSR in the design and manufacture of adjustable pedals. As noted, it is the exclusive licensee of the Engelgau patent. Engelgau filed the patent application on August 22, 2000 as a continuation of a previous

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application for U.S. Patent No. 6,109,241, which was filed on January 26, 1999. He has sworn he invented the patent's subject matter on February 14, 1998. The Engelgau patent discloses an adjustable electronic pedal described in the specification as a "simplified vehicle control pedal assembly that is less expensive, and which uses fewer parts and is easier to package within the vehicle." Engelgau, col. 2, lines 2–5, Supplemental App. 6. Claim 4 of the patent, at issue here, describes:

"A vehicle control pedal apparatus comprising:

a support adapted to be mounted to a vehicle structure;

an adjustable pedal assembly having a pedal arm moveable in for[e] and aft directions with respect to said support;

a pivot for pivotally supporting said adjustable pedal assembly with respect to said support and defining a pivot axis; and

an electronic control attached to said support for controlling a vehicle system;

said apparatus characterized by said electronic control being responsive to said pivot for providing a signal that corresponds to pedal arm position as said pedal arm pivots about said pivot axis between rest and applied positions wherein the position of said pivot remains constant while said pedal arm moves in fore and aft directions with respect to said pivot." *Id.*, col. 6, lines 17–36, Supplemental App. 8 (diagram numbers omitted).

We agree with the District Court that the claim discloses "a position-adjustable pedal assembly with an electronic pedal position sensor attached to the support member of the pedal assembly. Attaching the sensor to the support member allows the sensor to remain in a fixed position while the driver adjusts the pedal." 298 F.Supp.2d, at 586–587.

Before issuing the Engelgau patent the U.S. Patent and Trademark Office (PTO)rejected one of the patent claims that was similar to, but broader than, the present claim 4. The claim did not include the requirement that the sensor be placed on a fixed pivot point. The PTO concluded the claim was an obvious combination of the prior art disclosed in Redding and Smith, explaining:

"'Since the prior ar[t] references are from the field of endeavor, the purpose disclosed ... would have been recognized in the pertinent art of Redding. Therefore it would have been obvious ... to provide the device of Redding with the ... means attached to a support member as taught by Smith.'" *Id.*, at 595.

In other words Redding provided an example of an adjustable pedal and Smith explained how to mount a sensor on a pedal's support structure, and the rejected patent claim merely put these two teachings together.

Although the broader claim was rejected, claim 4 was later allowed because it included the limitation of a fixed pivot point, which distinguished the design from Redding's. *Ibid*. Engelgau had not included Asano among the prior art references, and Asano was not mentioned in the patent's prosecution. Thus, the PTO did not have before it an adjustable pedal with a fixed pivot point. The patent issued on May 29, 2001 and was assigned to Teleflex.

Upon learning of KSR's design for GM, Teleflex sent a warning letter informing KSR that its proposal would violate the Engelgau patent. "'Teleflex believes that any supplier of a product that combines an adjustable pedal with an electronic throttle control necessarily employs technology covered by one or more' " of Teleflex's patents. *Id.*, at 585. KSR refused to enter a royalty arrangement with Teleflex; so Teleflex sued for infringement, asserting KSR's pedal infringed the Engelgau patent and two other patents. *Ibid.* Teleflex later abandoned its claims regarding the other patents and dedicated the patents to the public. The remaining contention was that KSR's pedal system for GM infringed claim 4 of the Engelgau patent. Teleflex has not argued that the other three claims of the patent are infringed by KSR's pedal, nor has Teleflex argued that the mechanical adjustable pedal designed by KSR for Ford infringed any of its patents.

C

The District Court granted summary judgment in KSR's favor. After reviewing the pertinent history of pedal design, the scope of the Engelgau patent, and the relevant prior art, the court considered the validity of the contested claim. By direction of 35 U.S.C. § 282, an issued patent is presumed valid. The District Court applied *Graham*'s framework to determine

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whether under summary-judgment standards KSR had overcome the presumption and demonstrated that claim 4 was obvious in light of the prior art in existence when the claimed subject matter was invented. See § 102(a).

The District Court determined, in light of the expert testimony and the parties' stipulations, that the level of ordinary skill in pedal design was " 'an undergraduate degree in mechanical engineering (or an equivalent amount of industry experience) [and]familiarity with pedal control systems for vehicles.' "298 F.Supp.2d, at 590. The court then set forth the relevant prior art, including the patents and pedal designs described above.

Following *Graham*'s direction, the court compared the teachings of the prior art to the claims of Engelgau. It found "little difference." 298 F.Supp.2d, at 590. As ano taught everything contained in claim 4 except the use of a sensor to detect the pedal's position and transmit it to the computer controlling the throttle. That additional aspect was revealed in sources such as the '068 patent and the sensors used by Chevrolet.

Under the controlling cases from the Court of Appeals for the Federal Circuit, however, the District Court was not permitted to stop there. The court was required also to apply the TSM test. The District Court held KSR had satisfied the test. It reasoned (1) the state of the industry would lead inevitably to combinations of electronic sensors and adjustable pedals, (2) Rixon provided the basis for these developments, and (3)Smith taught a solution to the wire chafing problems in Rixon, namely locating the sensor on the fixed structure of the pedal. This could lead to the combination of Asano, or a pedal like it, with a pedal position sensor.

The conclusion that the Engelgau design was obvious was supported, in the District Court's view, by the PTO's rejection of the broader version of claim 4. Had Engelgau included Asano in his patent application, it reasoned, the PTO would have found claim 4 to be an obvious combination of Asano and Smith, as it had found the broader version an obvious combination of Redding and Smith. As a final matter, the District Court held that the secondary factor of Teleflex's commercial success with pedals based on Engelgau's design did not alter its conclusion. The District Court granted summary judgment for KSR.

With principal reliance on the TSM test, the Court of Appeals reversed. It ruled the District Court had not been strict enough in applying the test, having failed to make "'finding[s] as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of [the] invention' ... to attach an electronic control to the support bracket of the Asano assembly." 119 Fed. Appx., at 288 (brackets in original) (quoting *In re Kotzab*, 217 F.3d 1365, 1371 [55 USPQ2d 1313] (CA Fed. 2000)). The Court of Appeals held that the District Court was incorrect that the nature of the problem Copyright 2010, The Bureau of National Affairs, Inc.

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to be solved satisfied this requirement because unless the "prior art references address[ed]the precise problem that the patentee was trying to solve,"the problem would not motivate an inventor to look at those references, 119 Fed. Appx., at 288.

Here, the Court of Appeals found, the Asano pedal was designed to solve the "constant ratio problem"—that is, to ensure that the force required to depress the pedal is the same no matter how the pedal is adjusted—whereas Engelgau sought to provide a simpler, smaller, cheaper adjustable electronic pedal. *Ibid.* As for Rixon, the court explained, that pedal suffered from the problem of wire chafing but was not designed to solve it. In the court's view Rixon did not teach anything helpful to Engelgau's purpose. Smith, in turn, did not relate to adjustable pedals and did not "necessarily go to the issue of motivation to attach the electronic control on the support bracket of the pedal assembly." *Ibid.* When the patents were interpreted in this way, the Court of Appeals held, they would not have led a person of ordinary skill to put a sensor on the sort of pedal described in Asano.

That it might have been obvious to try the combination of Asano and a sensor was likewise irrelevant, in the court's view, because "'"[o]bvious to try" has long been held not to constitute obviousness.'" *Id.*, at 289 (quoting *In re Deuel*, 51 F.3d 1552, 1559 [34 USPQ2d 1210] (CA Fed. 1995)).

The Court of Appeals also faulted the District Court's consideration of the PTO's rejection of the broader version of claim 4. The District Court's role, the Court of Appeals explained, was not to speculate regarding what the PTO might have done had the Engelgau patent mentioned Asano. Rather, the court held, the District Court was obliged first to

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presume that the issued patent was valid and then to render its own independent judgment of obviousness based on a review of the prior art. The fact that the PTO had rejected the broader version of claim 4, the Court of Appeals said, had no place in that analysis.

The Court of Appeals further held that genuine issues of material fact precluded summary judgment. Teleflex had proffered statements from one expert that claim 4 " 'was a simple, elegant, and novel combination of features,' " 119 Fed. Appx., at 290, compared to Rixon, and from another expert that claim 4 was nonobvious because, unlike in Rixon, the sensor was mounted on the support bracket rather than the pedal itself. This evidence, the court concluded, sufficed to require a trial.

11

A

[1] We begin by rejecting the rigid approach of the Court of Appeals. Throughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test here. To be sure, *Graham* recognized the need for "uniformity and definiteness." 383 U.S., at 18. Yet the principles laid down in *Graham* reaffirmed the "functional approach" of *Hotchkiss*, 11 How. 248. See 383 U.S., at 12. To this end, *Graham* set forth a broad inquiry and invited courts, where appropriate, to look at any secondary considerations that would prove instructive. *Id.*, at 17.

Neither the enactment of § 103 nor the analysis in *Graham* disturbed this Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art. For over a half century, the Court has held that a "patent for a combination which only unites old elements with no change in their respective functions ...obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152 [87 USPQ 303] (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. Three cases decided after *Graham* illustrate the application of this doctrine.

In *United States* v. *Adams*, 383 U.S. 39, 40 [148 USPQ 479](1966), a companion case to *Graham*, the Court considered the obviousness of a "wet battery" that varied from prior designs in two ways: It contained water, rather than the acids conventionally employed in storage batteries; and its electrodes were magnesium and cuprous chloride, rather than zinc and silver chloride. The Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result. 383 U.S., at 50–51. It nevertheless rejected the Government's claim that Adams's battery was obvious. The Court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *Id.*, at 51–52. When Adams designed his battery, the prior art warned that risks were involved in using the types of electrodes he employed. The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams's design was not obvious to those skilled in the art.

In Anderson's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57 [163 USPQ 673] (1969), the Court elaborated on this approach. The subject matter of the patent before the Court was a device combining two pre-existing elements:a radiant-heat burner and a paving machine. The device, the Court concluded, did not create some new synergy: The radiant-heat burner functioned just as a burner was expected to function; and the paving machine did the same. The two in combination did no more than they would in separate, sequential operation. *Id.*, at 60–62. In those circumstances, "while the combination of old elements performed a useful function, it added nothing to the nature and quality of the radiant-heat burner already patented,"and the patent failed under § 103. *Id.*, at 62 (footnote omitted).

Finally, in Sakraida v. AG Pro, Inc., 425 U.S. 273 [189 USPQ 449] (1976), the Court derived from the precedents the conclusion that when a patent "simply arranges old elements with each performing the same function it had been known to perform" and yields no

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more than one would expect from such an arrangement, the combination is obvious. Id., at 282.

- [2] The principles underlying these cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. Sakraida and Anderson's-Black Rock are illustrative—a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.
- [3] Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 [78 USPQ2d 1329] (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

[4] When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight. See Application of Bergel, 292 F.2d 955, 956-957[130 USPQ 206](1961). As is clear from cases such as Adams, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

In the years since the Court of Customs and Patent Appeals set forth the essence of the TSM test, the Court of Appeals no doubt has applied the test in accord with these principles in many cases. There is no necessary inconsistency between the idea underlying the TSM test and the Graham analysis. But when a court transforms the general principle into a

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rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.

C

The flaws in the analysis of the Court of Appeals relate for the most part to the court's narrow conception of the obviousness inquiry reflected in its application of the TSM test. In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103. One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims.

[5] The first error of the Court of Appeals in this case was to foreclose this reasoning by holding that courts and patent examiners should look only to the problem the patentee was trying to solve. 119 Fed. Appx., at 288. The Court of Appeals failed to recognize that the problem motivating the patentee may be only one of many addressed by the patent's subject matter. The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art. Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

The second error of the Court of Appeals lay in its assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem. Ibid. The primary purpose of Asano was solving the constant ratio problem; so, the court concluded, an inventor considering how to put a sensor on an adjustable pedal would have no reason to consider putting it on the Asano pedal. Ibid. Common sense teaches, however, that familiar items may have Copyright 2010, The Bureau of National Affairs, Inc.

obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle. Regardless of Asano's primary purpose, the design provided an obvious example of an adjustable pedal with a fixed pivot point; and the prior art was replete with patents indicating that a fixed pivot point was an ideal mount for a sensor. The idea that a designer hoping to make an adjustable electronic pedal would ignore Asano because Asano was designed to solve the constant ratio problem makes little sense. A person of ordinary skill is also a person of ordinary creativity, not an automaton.

[6] The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

The Court of Appeals, finally, drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. See Graham, 383 U.S., at 36 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to " 'guard against slipping into the use of hindsight' "(quoting Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co., 332 F.2d 406, 412[141 USPQ 549](CA6 1964))). Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.

We note the Court of Appeals has since elaborated a broader conception of the TSM test than was applied in the instant matter. See, e.g., DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co., 464 F.3d 1356, 1367 [80 USPQ2d 1641] (2006) ("Our suggestion test is in actuality quite flexible and not only permits, but requires, consideration of common knowledge and common sense"); Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286, 1291 [80 USPQ2d 1001] (2006)("There is flexibility in our obviousness jurisprudence because a motivation may be found implicitly in the prior art. We do not

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have a rigid test that requires an actual teaching to combine ..."). Those decisions, of course, are not now before us and do not correct the errors of law made by the Court of Appeals in this case. The extent to which they may describe an analysis more consistent with our earlier precedents and our decision here is a matter for the Court of Appeals to consider in its future cases. What we hold is that the fundamental misunderstandings identified above led the Court of Appeals in this case to apply a test inconsistent with our patent law decisions.

Ш

When we apply the standards we have explained to the instant facts, claim 4 must be found obvious. We agree with and adopt the District Court's recitation of the relevant prior art and its determination of the level of ordinary skill in the field. As did the District Court, we see little difference between the teachings of Asano and Smith and the adjustable electronic pedal disclosed in claim 4 of the Engelgau patent. A person having ordinary skill in the art could have combined Asano with a pedal position sensor in a fashion encompassed by claim 4, and would have seen the benefits of doing so.

A

Teleflex argues in passing that the Asano pedal cannot be combined with a sensor in the manner described by claim 4 because of the design of Asano's pivot mechanisms. See Brief for Respondents 48-49, and n. 17. Therefore, Teleflex reasons, even if adding a sensor to Asano was obvious, that does not establish that claim 4 encompasses obvious subject matter. This argument was not, however, raised Copyright 2010, The Bureau of National Affairs, Inc.

before the District Court. There Teleflex was content to assert only that the problem motivating the invention claimed by the Engelgau patent would not lead to the solution of combining of Asano with a sensor. See Teleflex's Response to KSR's Motion for Summary Judgment of Invalidity in No. 02–74586 (ED Mich.), pp. 18–20, App. 144a–146a. It is also unclear whether the current argument was raised before the Court of Appeals, where Teleflex advanced the nonspecific, conclusory contention that combining Asano with a sensor would not satisfy the limitations of claim 4. See Brief for Plaintiffs-Appellants in No. 04–1152 (CA Fed.), pp. 42–44. Teleflex's own expert declarations, moreover, do not support the point Teleflex now raises. See Declaration of Clark J. Radcliffe, Ph.D., Supplemental App. 204–207; Declaration of Timothy L. Andresen, *id.*, at 208–210. The only statement in either declaration that might bear on the argument is found in the Radcliffe declaration:

"Asano ... and Rixon ... are complex mechanical linkage-based devices that are expensive to produce and assemble and difficult to package. It is exactly these difficulties with prior art designs that [Engelgau] resolves. The use of an adjustable pedal with a single pivot reflecting pedal position combined with an electronic control mounted between the support and the adjustment assembly at that pivot was a simple, elegant, and novel combination of features in the Engelgau '565 patent." *Id.*, at 206, ¶ 16.

Read in the context of the declaration as a whole this is best interpreted to mean that Asano could not be used to solve "[t]he problem addressed by Engelgau '565[:]to provide a less expensive, more quickly assembled, and smaller package adjustable pedal assembly with electronic control." *Id.*, at 205, ¶ 10.

The District Court found that combining Asano with a pivot-mounted pedal position sensor fell within the scope of claim 4. 298 F.Supp.2d, at 592–593. Given the sigificance of that finding to the District Court's judgment, it is apparent that Teleflex would have made clearer challenges to it if it intended to preserve this claim. In light of Teleflex's failure to raise the argument in a clear fashion, and the silence of the Court of Appeals on the issue, we take the District Court's conclusion on the point to be correct.

В

[7] The District Court was correct to conclude that, as of the time Engelgau designed the subject matter in claim 4, it was obvious to a person of ordinary skill to combine Asano with a pivot-mounted pedal position sensor. There then existed a marketplace that created a strong incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for achieving this advance. The Court of Appeals considered the issue too narrowly by, in effect, asking whether a pedal designer writing on a blank slate would have chosen both Asano and a

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modular sensor similar to the ones used in the Chevrolet truckline and disclosed in the '068 patent. The District Court employed this narrow inquiry as well, though it reached the correct result nevertheless. The proper question to have asked was whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading Asano with a sensor.

In automotive design, as in many other fields, the interaction of multiple components means that changing one component often requires the others to be modified as well. Technological developments made it clear that engines using computer-controlled throttles would become standard. As a result, designers might have decided to design new pedals from scratch; but they also would have had reason to make pre-existing pedals work with the new engines. Indeed, upgrading its own pre-existing model led KSR to design the pedal now accused of infringing the Engelgau patent.

For a designer starting with Asano, the question was where to attach the sensor. The consequent legal question, then, is whether a pedal designer of ordinary skill starting with Asano would have found it obvious to put the sensor on a fixed pivot point. The prior art discussed above leads us to the conclusion that attaching the sensor where both KSR and Engelgau put it would have been obvious to a person of Copyright 2010, The Bureau of National Affairs, Inc.

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ordinary skill.

The '936 patent taught the utility of putting the sensor on the pedal device, not in the engine. Smith, in turn, explained to put the sensor not on the pedal's footpad but instead on its support structure. And from the known wire-chafing problems of Rixon, and Smith's teaching that "the pedal assemblies must not precipitate any motion in the connecting wires," Smith, col. 1, lines 35–37, Supplemental App. 274, the designer would know to place the sensor on a nonmoving part of the pedal structure. The most obvious nonmoving point on the structure from which a sensor can easily detect the pedal's position is a pivot point. The designer, accordingly, would follow Smith in mounting the sensor on a pivot, thereby designing an adjustable electronic pedal covered by claim 4.

Just as it was possible to begin with the objective to upgrade Asano to work with a computer-controlled throttle, so too was it possible to take an adjustable electronic pedal like Rixon and seek an improvement that would avoid the wire-chafing problem. Following similar steps to those just explained, a designer would learn from Smith to avoid sensor movement and would come, thereby, to Asano because Asano disclosed an adjustable pedal with a fixed pivot.

Teleflex indirectly argues that the prior art taught away from attaching a sensor to Asano because Asano in its view is bulky, complex, and expensive. The only evidence Teleflex marshals in support of this argument, however, is the Radcliffe declaration, which merely indicates that Asano would not have solved Engelgau's goal of making a small, simple, and inexpensive pedal. What the declaration does not indicate is that Asano was somehow so flawed that there was no reason to upgrade it, or pedals like it, to be compatible with modern engines. Indeed, Teleflex's own declarations refute this conclusion. Dr. Radcliffe states that Rixon suffered from the same bulk and complexity as did Asano. See *id.*, at 206. Teleflex's other expert, however, explained that Rixon was itself designed by adding a sensor to a pre-existing mechanical pedal. See *id.*, at 209. If Rixon's base pedal was not too flawed to upgrade, then Dr. Radcliffe's declaration does not show Asano was either. Teleflex may have made a plausible argument that Asano is inefficient as compared to Engelgau's preferred embodiment, but to judge Asano against Engelgau would be to engage in the very hindsight bias Teleflex rightly urges must be avoided. Accordingly, Teleflex has not shown anything in the prior art that taught away from the use of Asano.

Like the District Court, finally, we conclude Teleflex has shown no secondary factors to dislodge the determination that claim 4 is obvious. Proper application of *Graham* and our other precedents to these facts therefore leads to the conclusion that claim 4 encompassed obvious subject matter. As a result, the claim fails to meet the requirement of § 103.

We need not reach the question whether the failure to disclose Asano during the prosecution of Engelgau voids the presumption of validity given to issued patents, for claim 4 is obvious despite the presumption. We nevertheless think it appropriate to note that the rationale underlying the presumption—that the PTO, in its expertise, has approved the claim—seems much diminished here.

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IV

[8] A separate ground the Court of Appeals gave for reversing the order for summary judgment was the existence of a dispute over an issue of material fact. We disagree with the Court of Appeals on this point as well. To the extent the court understood the *Graham* approach to exclude the possibility of summary judgment when an expert provides a conclusory affidavit addressing the question of obviousness, it misunderstood the role expert testimony plays in the analysis. In considering summary judgment on that question the district court can and should take into account expert testimony, which may resolve or keep open certain questions of fact. That is not the end of the issue, however. The ultimate judgment of obviousness is a legal determination. *Graham*, 383 U.S., at 17. Where, as here, the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and Copyright 2010, The Bureau of National Affairs, Inc.

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the obviousness of the claim is apparent in light of these factors, summary judgment is appropriate. Nothing in the declarations proffered by Teleflex prevented the District Court from reaching the careful conclusions underlying its order for summary judgment in this case.

We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts. See U.S. Const., Art. I, § 8, cl. 8. These premises led to the bar on patents claiming obvious subject matter established in Hotchkiss and codified in § 103. Application of the bar must not be confined within a test or formulation too constrained to serve its purpose.

KSR provided convincing evidence that mounting a modular sensor on a fixed pivot point of the Asano pedal was a design step well within the grasp of a person of ordinary skill in the relevant art. Its arguments, and the record, demonstrate that claim 4 of the Engelgau patent is obvious. In rejecting the District Court's rulings, the Court of Appeals analyzed the issue in a narrow, rigid manner inconsistent with § 103 and our precedents. The judgment of the Court of Appeals is reversed, and the case remanded for further proceedings consistent with this opinion.

It is so ordered.

- End of Case -

RELATED PROCEEDINGS APPENDIX XII

None